Evidence Table 57. General characteristics of all studies

| **Author Year** | **Population** | **Study** | **CVD Drug** | **Dietary Supplements** | **Control Group(s)** | **Other Interventions** |
| --- | --- | --- | --- | --- | --- | --- |
| Abdul 20101 | N screened: NR  N included/randomized: 12  Age: 24  %female: 0  Ethnicity:  - Caucasian (6)  - Asian (6)  Comorbidities (other than indication(s) for CVDs: NR  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: non-smokers and not taking any medication including any herbal medicines or dietary supplements (for at least 2 weeks)  Exclusion Criteria: Subjects with any medical condition that could alter warfarin effects, including any clotting disorders, hepatic dysfunction or platelet dysfunction  Brief Description: healthy male subjects of known CYP2C9 and VKORC1 genotype | Study Design: Crossover RCT  Region: NR, likely Australia  Setting: NR  Industry Funded: Yes  Treatment Duration supplement(s): 21  Treatment DurationCVD Drug(s): Single dose  Duration of Followup: 7  Duration of Longest Followup: 7 | Generic Name(s): warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: 25mg- 1 dose  Reason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 12  Supplement(s): Echinacea  Form of Administration: Capsule/Tablet  Daily Dose: 5100 mg | N1 = 12  No treatment  N2 = 12  policosanol (non-relevant supplement) | Non-CVD Medications: NA  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |

| Evidence Table 57. General characteristics of all studies (continued) | | | | | | |
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| **Author Year** | **Population** | **Study** | **CVD Drug** | **Dietary Supplements** | **Control Group(s)** | **Other Interventions** |
| Aruna  20072 | N screened: 16  N included/randomized: 10  Age: 27  %female: 0  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: NR  Exclusion Criteria: subjects hypersensitive to study drugs, chronic smokers or alcoholics, and a history of gastrointestinal surgery that could interfere with absorption of study drugs  Brief Description: healthy male subjects | Study Design: Crossover RCT  Region: Rest of Asia  Setting: General community  Industry Funded: Unclear  Treatment Duration supplement(s): 1  Treatment DurationCVD Drug(s): 1  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): cilostazol  Drug Category: Vasodilator: Nitrates/PDE-5 Inhibitors  Mode of Administration: Oral  Mean Daily Dose: 150mg  Reason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study  Generic Name(s): clopidogrel  Drug Category: Antiplatelets Mode of Administration: Oral  Mean Daily Dose: 112.5mg  Reason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 10  Supplement(s): Gingko biloba  Form of Administration: Capsule/Tablet  Daily Dose: 120mg single dose | N1 = 10  No treatment  N2 = 10  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Avogaro  19743 | N screened: NR  N included/randomized: 20  Age: NR  %female: NR  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: suffering from hyperlipoproteinemia; high levels of cholesterol and/or serum triglycerides at least twice after being on a balanced diet for two weeks. Classified on the basis of lipids and lipoproteins levels according to the criteria of Fredrickson et al. and recommendations of the WHO  Exclusion Criteria: NR  Brief Description: Patients suffering from hyperlipoproteinemia | Study Design: Crossover RCT  Region: Europe  Setting: Primary care  Industry Funded: Unclear  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 28  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  propranolol  Drug Category: b-blockers  Mode of Administration: Oral  Mean Daily Dose: 20mg OR 60mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 20  Supplement(s): Niacin  Form of Administration: Capsule/tablet  Daily Dose: 250 mg (and non-relevant dose of 750mg/day) | N1 = 20  Placebo  N2 = 20  No treatment  N3 = 20  Intervention3:  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): diet adjusted to bring each patient to ideal weight. The diet provided 45 % carbohydrates, 34 % fats, I5 % proteins and 6 % alcohol; 78% of carbohydrates was given as starches and 22% as sugars. For fats the P/S relationship was 1.87; the amount of dietary cholesterol did not exceed 200 mg.  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Balestrieri  19964 | N screened: NR  N included/randomized: 16  Age: 42.5  %female: 44  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: Heterozygous FH diagnosed according to the criteria of Brown and Goldstein; normal thyroid, renal and hepatic function  Exclusion Criteria: diabetic, obese  Brief Description: Group of heterozygous FH patients on long-term treatment with simvastatin | Study Design: Crossover RCT  Region: Europe  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 28  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  Simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: range 10-40mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 8  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/tablet  Daily Dose: 5100mg | N1 = 8  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): lipid lowering diet (Step 1 AHA diet)  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Barbagallo  19995 | N screened: NR  N included/randomized: 24  Age: 47.05  %female: 54  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Essential hypertension (outpatient blood pressure >140/90 mm Hg on >/=3 occasions and the absence of any history, physical examination, or laboratory evidence of secondary forms of hypertension)  Exclusion Criteria: Patients with diabetes  mellitus or glucose intolerance  Brief Description: Patients with essential hypertension | Study Design: Parallel RCT  Region: Europe  Setting: Primary care  Industry Funded: Unclear  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 28  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  furosemide  Drug Category: Diuretic: Loop  Mode of Administration: Oral  Mean Daily Dose: 25mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 12  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 600mg | N1 = 12  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Bays  20106 | N screened: 585  N included/randomized: 245  Age: 56.15  %female: 42  Ethnicity: Caucasian (89)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: Between ages 18-79;medically stable; Lipid criteria: non-HDL-C level greater than 160mg/dL and triglycerides between 250 and 599 mg/dL  Exclusion Criteria: Use of nonstudy lipid lowering therapy;omega3 supplements;or niacin dosages >400; known allergy to statins or omega3s; symptoms of muscle pain, tenderness or weakness 2mo before study; history of myopathy or rhabdomyolysis  Brief Description: patients with combined hyperlipidemia | Study Design: Parallel RCT  Region: North America  Setting: Specialty clinic  Industry Funded:  Yes  Treatment Duration supplement(s): 112  Treatment DurationCVD Drug(s): 112  Duration of Followup: End of treatment period  Duration of Longest Followup: NR | Generic Name(s): atorvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 10, 20 and 40mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 123  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose:: 4000mg | N1 = 122  Placebo plus atorvastatin | Non-CVD Medications: none  Dietary Intervention(s): National Cholesterol Education Program therapeutic lifestyle changes diet  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Bays  20097 | N screened: 596  N included/randomized: 167  Age: 52.05  %female: 26.35  Ethnicity:  - Caucasian (88)  - African-American (1)  - Hispanic (7)  - Other (4)  Comorbidities (other than indication(s) for CVDs): overweight/obese; Type II Diabetes (20.5%)  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: men and women in good health between 18 and 79 years of age with a body mass index of >/=25 kg/m2 and </=43 kg/m2; mean fasting TG level of >/=500 mg/dL and <1300 mg/dL as determined by the average of the 2 TG values obtained at 2 weeks before and 1 week prior to randomization; met the criteria for Fredrickson type IV dyslipidemia  Exclusion Criteria: use of warfarin, cyclic sex hormone therapy, or other agents known to affect lipid levels during the run-in or treatment period of the study; The use of cyclosporine, systemic corticosteroids, high-dose topical corticosteroids (1500 mg/d), androgens, phenytoin, isotretinoin, or thyroid hormones (except stable-dose replacement therapy for 2 months prior to week 6) during the study also was restricted. Subjects with a known sensitivity to seafood, EPA or DHA, in addition to any history of pancreatitis, significant renal, hepatic, biliary, or gastrointestinal disease, type 1 diabetes mellitus, or uncontrolled type 2 diabetes; Women who were pregnant, lactating, or were of childbearing potential and were not using a medically approved method of contraception  Brief Description: 18-75 years old, overweight/obese, with dyslipidemia | Study Design: Parallel RCT  Region: North America  Setting: Not reported  Industry Funded: Yes  Treatment Duration  supplement(s): 56  Treatment DurationCVD Drug(s): 56  Duration of Followup: 56  Duration of Longest Followup: End of treatment period | Generic Name(s): fenofibrate  Drug Category: Antilipidemic: Fibrate  Mode of Administration: Oral  Mean Daily Dose: 130mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 75  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 75  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): low saturated fat NCEP Therapeutic Lifestyle Changes (TLC) diet  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Bender  19988 | N screened: NR  N included/randomized: 16  Age: 53.5  %female: 54.5  Ethnicity:  - African-American (9)  - Hispanic (91)  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: Unclear  Inclusion Criteria: between the ages of 18 and 70years, stable anticoagulation status (i.e., INR change no greater than1.63 for at least the past 3 consecutive months, with no warfarin dosage adjustments).  Exclusion Criteria: any new medication(s) other  than the study medications within 1 month of the  study, receiving concurrent therapy with salicylates or other nonsteroidal anti-inflammatory agents,  baseline platelet count less than100,000, history of a major bleeding episode while receiving warfarin therapy within the past 5 years, had active peptic ulcer disease within the previous 6 months, or  cerebrovascular disease, uncontrolled hypertension, or surgery/trauma within the previous 3 months. Women who were pregnant or of child-bearing potential who were not using an acceptable means of contraception  Brief Description:Patients receiving chronic warfarin therapy for indications requiring oral anticoagulation | Study Design: Parallel RCT  Region: North America  Setting:  Industry Funded: Unclear  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 28  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 3000 or 6000mg | Placebo (matching; R.P. Schering Pharmaceuticals  Corporation) | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Bordia  19989 | N screened: NR  N included/randomized: 60  Age: NR  %female: NR  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At high risk for CHD  Inclusion Criteria: Patients with CAD and with old healed MI (> 6 months) with or without angina.  Exclusion Criteria: NR  Brief Description: Patients with CAD | Study Design: Controlled clinical trial (CCT)  Region: Europe  Setting: Not reported  Industry Funded: No  Treatment Duration supplement(s): 90  Treatment DurationCVD Drug(s): Unclear  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  Nitrates  Drug Category: Vasodilator: Nitrates/PDE-5 Inhibitors  Mode of Administration: NR  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 30  Supplement(s): Garlic  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 30  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Budoff 200410 | N screened: NR  N included/randomized: 23  Age: 59.6  %female: 26  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At high risk for CHD  Inclusion Criteria: known coronary artery disease or high risk for coronary artery disease, with a 10-year Framingham risk of developing coronary artery disease of >20%  Exclusion Criteria: A contraindication to Aged Garlic Extract therapy including: known hypersensitivity to drug; Weight in excess of 300 lb; Serum creatinine >1.4 mg/d; Triglycerides >400 at visit; Drug or alcohol abuse, or current intake of more than 14 standard drinks per week; Concurrent enrollment in another placebo-controlled  Trial; Presence of metal clips or stenting that preclude accurate measure of coronary calcification and angiographic disease by electron beam tomography; Partial ileal bypass or known gastrointestinal disease limiting drug absorption; Current intake of garlic supplement  Brief Description: patients with known coronary artery disease or high risk for coronary artery disease | Study Design: Parallel RCT  Region: NR, likely North America  Setting: NR  Industry Funded: Unclear  Treatment Duration supplement(s): 365  Treatment DurationCVD Drug(s): 365  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Statin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: NR  Mean Daily Dose: Range of 10-40mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 9  Supplement(s): Garlic  Form of Administration: Liquid  Daily Dose: 4 ml | N1 = 10  Placebo  N2 = NA  NA | Non-CVD Medications: NR  Dietary Intervention(s): All participants were educated on a low-cholesterol diet at entry to the study by the nurse coordinator  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Caso  200711 | N screened: NR  N included/randomized: 32  Age: 60.63  %female: 47  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: treated for hyperlipidemia with statin; under current NCEP guidelines and reporting myopathic symptoms (only if no other identifiable cause of myopathy could be determined)  Exclusion Criteria: Clinical evidence of hepatic, vascular, renal or endocrine disease;coagulopathy; or other serious medical conditions; none were using CoQ10, Vit E or anticoagulants  Brief Description: patients using statins with myopathic pain | Study Design: Parallel RCT  Region: North America  Setting: Speciality clinic  Industry Funded: No  Treatment Duration supplement(s): 30  Treatment DurationCVD Drug(s): 30  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  Simvastatin (22); Atorvastatin (7); Pravastatin (2); Lovastatin (1)  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: varying doses for all patients  Reason for taking CVD drug(s): Cardiovascular indication | N: 18  Supplement(s): Coenzyme Q10  Form of Administration: Capsule/Tablet  Daily Dose: 100mg | N1 = 14  Vitamin E, 400IU | Non-CVD Medications: nonsteroidal anti-inflammatory drugs taken by 9 patients  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): patients were already following Adult Treatment Panel III/National Cholesterol Education Program guidelines |
| Chan  200212 | N screened: 52  N included/randomized: 52  Age: 53.23  %female: 0  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): obese  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: obese (BMI>29kgm-2); dyslipidemia (LDL-C>2.6mmol L-1, non HDL-C>3.4mmolL-1 and triglycerides>1.2mmolL-1); weight-maintenance diet  Exclusion Criteria: diabetes;apolipoprotein E2/D2 genotype;macroproteinuria;creatinaemia(>120umolL-1);hypothyroidism;abnormal liver and muscle enzymes; consumed fish oil supplements; more than 30g alcohol  Brief Description: viscerally obese men | Study Design: Parallel RCT  Region: NR  Setting: Not reported  Industry Funded: Yes  Treatment Duration supplement(s): 42  Treatment DurationCVD Drug(s): 42  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  Atorvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 40mg  Reason for taking CVD drug(s): Cardiovascular indication | N:  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 =  Placebo  N2 =  fish oil + atorvastatin placebo | Non-CVD Medications: NA  Dietary Intervention(s): isocaloric diet  Exercise Intervention(s): keep their physical activity constant  Other Lifestyle Intervention(s): No |
| d'Arcangues  200413 | N screened: NR  N included/randomized: 9297  Age: NR  %female: NR  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: healthy, between 18 and 38 years old, nonpregnant and nonlactating and had been using the implantable contraceptive Norplant for 1 to 6 months. Able to keep a menstrual diary, willing to return to the clinic at prescribed intervals, agreed not to use vitamins, aspirin, anti-inflammatory drugs, steroids or any other drug that might affect the vaginal bleeding pattern (other than those prescribed in the trial) during the trial or for 3 weeks prior to admission.  Exclusion Criteria: they had a last injection of DMPA within 6 months or a last injection of norethisterone enanthate (NET-EN) within 4 months, previous immediate use of Norplant or levonorgestrel-releasing intrauterine device, hemoglobin level lower than 8 g/dl,known hypersensitivity to aspirin or vitamin E or had participated in the pilot study of vitamin E previously conducted in Jakarta.  Brief Description: healthy bleeding with Norplant-induced prolonged vaginal bleeding | Study Design: Parallel RCT  Region: Multiple (East Asia, Central & South America)  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 10  Treatment DurationCVD Drug(s): 10  Duration of Followup: 360  Duration of Longest Followup: 360 | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 80mg  Reason for taking CVD drug(s): Norplant-induced prolonged vaginal bleeding | N: 120  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 200mg | N1 = 122  No treatment  N2 = 123  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Davidson  200714 | N screened: 690  N included/randomized: 256  Age: 59.8  %female: 42.5  Ethnicity: NR  - Caucasian (95.7)  - African-American (2)  - Hispanic (1.6)  - Asian (1.2)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: between ages 18-79;receiving stable does of statin for control of LDL-C levels for>8weeks;mean fasting T G level>200 and<500mg/dL, and a mean LDL-C level below or within 10% of the patient's NCEP ATP  Exclusion Criteria: poorly controlled diabetes (HbA1c>8%); history of CV; revascularization procedure or aortic aneurysm within 6mo of screening; history of pancreatitis;sensitivity to statins or omega3s;poorly controlled hypertension (resting blood pressure>160mmHg systolic and/or\_>100mm Hg; serum creatinine level\_>2.0 mg/dL;serum transaminase>1.5 times the upper limit of normal;creatine kinase levels>2 times the ULN  Brief Description: patients with persistent hypertriglyceridemia despite statin therapy | Study Design: Parallel RCT  Region: North America  Setting: Speciality clinic  Industry Funded: Yes  Treatment Duration supplement(s): 56  Treatment DurationCVD Drug(s): 112  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 40mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 123  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 133  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): NCEP Therapeutic Lifestyle Changes diet  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Davidson  199715 | N screened: 46  N included/randomized: 30  Age: NR  %female: NR  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Serum lipid values determined as mean values from 2 fasting measurements taken 1 week apart. Qualifying lipid concentrations were LDL cholesterol >/ 160 and </ 240 mg/dl, HDL </ 50mg/dl for men and </60 mg/dl for women, and fasting triglycerides of 200 to 600 mg/dl after >/ 4 weeks following a National Cholesterol Education Program Step I Diet.  Exclusion Criteria: NR  Brief Description: Hyperlipidemic subjects | Study Design: Parallel RCT  Region: NR  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 84  Treatment DurationCVD Drug(s): 84  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  Simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 10mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 10  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 10000mg | N1 = 10  No treatment  N2 = 9  Fish oil | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| De, Caterina  200216 | N screened: NR  N included/randomized: 43  Age: 63.1  %female: 51  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): diabetes (19%)  CHD Risk Level: At high risk for CHD  Inclusion Criteria: hypercholesterolemic subjects (Fredrickson IIa or IIb) with serum cholesterol 200 mg/dL and proven vascular (coronary, carotid, or peripheral arterial) disease.  Exclusion Criteria: NR  Brief Description: hypercholesterolemic subjects with proven vascular disease | Study Design: Crossover RCT  Treatment Duration: 30  Region: NR  Setting: Not reported  Industry Funded: Yes  Treatment Duration supplement(s): 30  Treatment DurationCVD Drug(s): 30  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 10mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 21  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 600mg | N1 = 22  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Dehmer  198817 | N screened: 149  N included/randomized: 90  Age: 56  %female: 0  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): diabetes 28% in control groupl; 21% in treatment group  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: male patients referred to laboratory for angioplasty  Exclusion Criteria: age over 80 years, severe confounding medical problems, angioplasties for restenosis that had developed after an earlier procedure; acute MI or unstable ischemic symptoms that persisted despite all medical therapies.  Brief Description: male patients undergoing angioplasty | Study Design: Parallel RCT  Region: North America  Setting: Speciality clinic  Industry Funded: No  Treatment Duration supplement(s): 187  Treatment DurationCVD Drug(s): 187  Duration of Followup: 270,360  Duration of Longest Followup: 360 | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 325mg  Reason for taking CVD drug(s): Cardiovascular indication  Generic Name: dipyridamole  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 225mg  Reason for taking CVD drug(s): Cardiovascular indication  Generic Name: NR  Drug Category: Calcium channel blockers  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 43  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 3200mg | N1 = 39  No treatment | Non-CVD Medications: NA  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Desideri  200318 | N screened: 67  N included/randomized: 67  Age: 47.7  %female: 42  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Serum LDL-cholesterol levels of more than 5.2 mmol/liter and less than 7.8 mmol/liter adn fasting triglycerdie levels of less than 1.7 mmol/liter after 30d on an American heart step I diet. Normal M-mode and B-mode echocardiograms and 12-lead electrocardiogram  Exclusion Criteria: age of less than 25 year or higher than 55 year, pregnancy, concomitant diseases, personal history of previous cerebro-or cardiovascular disease, diabetes of either type I or II, hypertension, obesity, smoking, drug consumption (including vitamins, aspritin, birth control) alcohol intake of more than 10g, proteinuria, serum reatine of more than 100microM or atherosclerotic lesions of the neck and limb vessels, Patients with allergic diasthesis regaring both type I adn type II immune responses and/or reporting respiratory, GI or genotourinary tracts infections during the last 3 months.  Brief Description: Hypercholesterolemic patients | Study Design: Parallel RCT  Region: Europe  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 180  Treatment DurationCVD Drug(s): 180  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  Simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 40mg  Reason for taking CVD drug(s):  Generic Name: NR  Bezafibrate  Drug Category: Antilipidemic: Fibrate  Mode of Administration: Oral  Mean Daily Dose: 800mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 31  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 400IU | N1 = 19  No treatment  N2 = 17  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Di Spirito 200819 | N screened: 50  N included/randomized: 50  Age: 35  %female: 20  Ethnicity:  - Caucasian (98)  - African-American (2)  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: NR  Exclusion Criteria: Women who were pregnant or lactating or who were planning a pregnancy; Individuals with a history of hypersensitivity or allergy to study medications  Brief Description: healthy non-smoking men and women within 15% of ideal body weight | Study Design: Crossover RCT  Region: North America  Setting: Research Facility  Industry Funded: Yes  Treatment Duration supplement(s): 14  Treatment DurationCVD Drug(s): 14  Duration of Followup: 1  Duration of Longest Followup: 1 | Generic Name(s): atorvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor Mode of Administration: Oral  Mean Daily Dose: 80mg  Reason for taking CVD drug(s): pharmacokinetics of atorvastatin and P-OM3 | N: 50  Supplement(s): Omega-3 (EPA, DHA or both)  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 50  No treatment | Non-CVD Medications: hormonal contraceptives (portion NR)  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Duffy  200120 | N screened: NR  N included/randomized: 29  Age: 28.7  %female: 54  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: hypercholesterolaemia (total cholesterol and LDL levels were above the 75th percentile for age and gender based on NHFA Risk Factor Prevalence Study)  Exclusion Criteria: any other risk factor for CAD, cardiovascular disease, any other major disease; volunteers on CV medications or vitamin supplements  Brief Description: young patients with hypercholesterolaemia | Study Design: Parallel RCT  Region: NR (likely Australia)  Setting: Not reported  Industry Funded: No  Treatment Duration supplement(s): 180  Treatment DurationCVD Drug(s): 180  Duration of Followup: End of treatment period  Duration of Longest Followup: : End of treatment period | Generic Name(s): NA  simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: starting dose 10mg; ending dose 40mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 6  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 1000 IU | N1 = 7  Placebo  N2 = 7  No treatment  N3 = 6  Intervention3: Vitamin E | Non-CVD Medications: estrogen-based oral contraceptives (portion of population)  Dietary Intervention(s): dietary advice and information sheets on cholesterol lowering diets  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Eritsland  199621 | N screened: NR  N included/randomized: 291  Age: 60.49  %female: 12.5  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Diabetes  CHD Risk Level: At high risk for CHD  Inclusion Criteria: admitted for coronary artery bypass grafting without concomitant cardiac surgery.  Exclusion Criteria: medical containdications to any of the treatment principles; refused participation; early (<2 days) perioperative death or complications; presumed lack of compliance; indication for anticoagulation; administrative reasons  Brief Description: Subjects undergoing coronary artery bypass grafting without surgery | Study Design: Parallel RCT  Region: Europe  Setting: Specialty Clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 365  Treatment DurationCVD Drug(s): 365  Duration of Followup: 365  Duration of Longest Followup: 365 | Generic Name(s):  ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 300mg  Reason for taking CVD drug(s): | N: 143  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 148  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): Verbal and written dietary advice; decreased intake of saturated fatty acids advised; told to refrain from cod-liver oil and other fish oil products; dietary records obtained from a random sample.  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Eritsland  199621 | N screened: NR  N included/randomized: 319  Age: 59.54  %female: 13.8  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Diabetes  CHD Risk Level: At high risk for CHD  Inclusion Criteria: admitted for coronary artery bypass grafting without concomitant cardiac surgery.  Exclusion Criteria: medical containdications to any of the treatment principles; refused participation; early (<2 days) perioperative death or complications; presumed lack of compliance; indication for anticoagulation; administrative reasons  Brief Description: Subjects undergoing coronary artery bypass grafting without surgery | Study Design: Parallel RCT  Region: Europe  Setting: Specialty Clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 365  Treatment DurationCVD Drug(s): 365  Duration of Followup: 365  Duration of Longest Followup: 365 | Generic Name(s):  warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 174  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 145  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): Verbal and written dietary advice; decreased intake of saturated fatty acids advised; told to refrain from cod-liver oil and other fish oil products; dietary records obtained from a random sample.  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Ferraro  200922 | N screened: NR  N included/randomized: 30  Age: 45  %female: 36.6  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: patients with biopsy-proven IgAN and persistent proteinuria (>200 mg) despite treatment with ACE inhibitors and/or ARB. only patients with at least two positive determinations were included  Exclusion Criteria: dialysis or kidney transplantation, diabetes mellitus, Henochâ€“Schoenlein purpura, systemic lupus erythematosus and an active or recent (<1 year) treatment with immunosuppressors and/or PUFA.  Brief Description: patients with biopsy-proven IgAN and persistent proteinuria | Study Design: Parallel RCT  Region: Europe  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 180  Treatment DurationCVD Drug(s): 180  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ramipril  Drug Category: RAAS Antagonist: ACEI  Mode of Administration: Oral  Mean Daily Dose: 10mg  Reason for taking CVD drug(s): IgA nephropathy | N: 15  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 3000mg | N1 = 15  No treatment | Non-CVD Medications: Steroid 60 days prior to randomization in 1 vs. 2 pts (Irbesartan 300mg)  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Gardner  200723 | N screened: 188  N included/randomized: 67  Age: 68.5  %female: 40  Ethnicity:  - Caucasian (75)  - African-American (5)  - Hispanic (13)  - Asian (7)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At high risk for CHD  Inclusion Criteria: experienced leg pain during walking that was characteristic of the intermittent claudication symptom of PAD, or who might be at risk for PAD due to either a family history of cardiovascular disease (CVD) or elevated CVD risk factors.Older than 18 years of age, had not been taking (for at least 1 month prior to randomization) and did not plan to take (for the duration of the study) any medications or dietary supplements known to affect blood coagulation, and were able to tolerate daily use of aspirin for 6 weeks.  Exclusion Criteria: NR  Brief Description: adult patients at risk for PAD not taking any medications known to affect blood coagulation and able to tolerate aspirin for 6 weeks | Study Design: Parallel RCT  Region:NR (likely North America)  Setting: Not reported  Industry Funded: Yes  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 42  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 325mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 29  Supplement(s): Gingko biloba  Form of Administration: Capsule/Tablet  Daily Dose: 300mg | N1 = 26  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Garg  199524 | N screened: 98  N included/randomized: 62  Age: 54.19  %female: 29.6  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): NR  CHD Risk Level: At high risk for CHD  Inclusion Criteria: acute ischemic stroke, either sex with sudden hemoplegia of either side with or without speech involvement, with cranial CT scan (non-contrast enhanced) showing a hypodense lesion (infarct) in the territory of either middle cerebral artery  Exclusion Criteria: ischemia in posterior cerebral territory, overt systemic disease (e.g. recent myocardial infarction, renal failure, severe systemic infection, deeply comatose.  Brief Description: patients with acute ischemic stroke | Study Design: Parallel RCT  Region: Rest of Asia  Setting: Primary care  Industry Funded: Unclear  Treatment Duration supplement(s): 7  Treatment DurationCVD Drug(s): Unclear  Duration of Followup: 14  Duration of Longest Followup: 14 | Generic Name(s):  ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 29  Supplement(s): Gingko biloba  Form of Administration: Capsule/Tablet  Daily Dose: 240mg | N1 = 26  Placebo | Non-CVD Medications: antibiotics and short-term glucocorticoids  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Glynn  200725 | N screened: 453787  N included/randomized: 65169  Age: NR  %female: 100  Ethnicity:  - Caucasian (94.8)  - African-American (2.3)  - Hispanic (1.1)  - Asian (1.4)  - Other (0.4)  Comorbidities (other than indication(s) for CVDs): Obesity (18%), Type II Diabetes (portion), women with deep vein thrombosis or pulmonary embolism were not excluded (portion NR)  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: age 45 years or older; no previous history of coronary heart disease, cerebrovascular disease, cancer (except nonmelanoma skin cancer), or other major chronic illnesses; no history of adverse effects from aspirin; no use of aspirin or nonsteroidal anti-inflammatory drugs (NSAIDs) more than once a week, or willingness to forgo their use; no use of anticoagulants or corticosteroids; and no use of individual supplements of vitamin A, E, or beta carotene more than once a week.  Exclusion Criteria: women who currently used anticoagulants  Brief Description: Healthy women not currently using anticoagulants | Study Design: Parallel RCT  Region: North America  Setting: General community  Industry Funded: Unclear  Treatment Duration supplement(s): 3650  Treatment DurationCVD Drug(s): 3650  Duration of Followup: 3650  Duration of Longest Followup: 3650 | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose:  100mg/every other day  Reason for taking CVD drug(s): prevention | N: 19,937  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 600IU/every other day | N1 = 19,939  Placebo | Non-CVD Medications: Hormone therapy (30%)  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Gosai  200826 | N screened: NR  N included/randomized: 48  Age: 37  %female: 25  Ethnicity:  - Caucasian (42)  - Other (arabic, african or undefined ethnicity) (6)  Comorbidities (other than indication(s) for CVDs: NR  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Healthy non-smoking men and women between the ages of 18 and 55 years who were within 15% of ideal body weight  Exclusion Criteria: Women who were pregnant, lactating, or planning a pregnancy; individuals with a history of hypersensitivity or allergy to study medications  Brief Description: healthy adult volunteers | Study Design: Crossover RCT  Region: NR  Setting: NR  Industry Funded: Yes  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 28  Duration of Followup: 1  Duration of Longest Followup: 1 | Generic Name(s): rosuvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 40mg  Reason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 48  Supplement(s): Omega-3 (EPA, DHA or both)  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 48  No treatment | Non-CVD Medications: hormonal contraceptives (portion NR)  Dietary Intervention(s): meal plans provided 4 and 9h after each dosing  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Govil 197927 | N screened: NR  N included/randomized: 80  Age: NR  %female: 31  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At high risk for CHD  Inclusion Criteria: congestive cardiac failure  Exclusion Criteria: renal insufficiency  Brief Description: patients of congestive cardiac failure | Study Design: Controlled Clinical Trial  Region: Rest of Asia  Setting: Primary Care  Industry Funded: Unclear  Treatment Duration supplement(s): NR  Treatment DurationCVD Drug(s): NR  Duration of Followup: 8  Duration of Longest Followup: 8 | Generic Name(s): Digoxin  Drug Category: Inotropics  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s):Cardiovascular indication  Generic Name(s): Diuretics  Drug Category: Diuretic: Loop  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s):Cardiovascular indication | N: 20  Supplement(s): Magnesium  Form of Administration: Liquid  Capsule/Tablet  Daily Dose: 396 mEq | N1 = 60  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Hajda, 201028 | N screened: NR  N included/randomized: 10  Age: 28.8  %female: 0  Ethnicity: Caucasian  Comorbidities (other than indication(s) for CVDs: None  CHD Risk Level: At low risk for CHD  Inclusion Criteria: healthy male subjects (based on physical examinations, standard clinical chemistry and hematology analyses)  Exclusion Criteria: NR  Brief Description: patients of congestive cardiac failure | Study Design: Randomized cross over (the design may not fit the exact description of RCT for this review)  Region: Europe  Setting: Unclear  Industry Funded: Yes  Treatment Duration supplement(s): 21 days  Treatment DurationCVD Drug(s): 21 days  Duration of Followup: 21 days  Duration of Longest Followup: 22 days | Generic Name(s): Statins (pravastatin, or simvastatin)  Mode of Administration: Oral  Daily Dose: 20 mg  Reason for taking CVD drug(s):non- Cardiovascular indication  Generic Name(s):  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): non-Cardiovascular indication | N: 10  Supplement(s): Garlic  Form of Administration: Capsule/Tablet  Daily Dose: 600 mg bid (twice daily) | N1 = 10  No treatment | Non-CVD Medications: No  Dietary Intervention(s): standardized meals during the study period; all subjects were instrucete to abstain from taking any type of medication, including overthe-counter remedies and supplements, grapefruit, caffeine, or alcohol-containing food or beverages for at least 3 days prior to the start of the study and throughout the course of the study.  Exercise Intervention(s): No  Other Lifestyle Intervention(s): NR |
| Hansen  199329 | N screened: NR  N included/randomized: 15  Age: 49  %female: 53.3  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): tendon xanthomas (3)  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: hypercholesterolemia, nonobese (within 15% of their ideal body weight) and had a total serum cholesterol level above 9.0 mmol/1 and a triglyceride level below 2.0 mmol/1 on two occasions after 8-20 weeks on a diet low in cholesterol and saturated fat (American Heart Association step I diet), normal thyroid, renal, and hepatic function, no diabetes, manifest cardiovascular disease, or other chronic illnesses  Exclusion Criteria: peptic ulcers, gastrointestinal disorders likely to influence drug absorption,  alcoholism, drug abuse, or mental illness  Brief Description: hypercholesterolemic patients within 15% of their ideal body weight | Study Design: Crossover RCT  Region: Europe  Setting: Primary care  Industry Funded: Unclear  Treatment Duration supplement(s): 42  Treatment DurationCVD Drug(s): 42  Duration of Followup: 84  Duration of Longest Followup: 84 | Generic Name(s): lovastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 40mg  Reason for taking CVD drug(s): Cardiovascular indication | N=15  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 6000mg | N=15  Placebo (olive oil) + lovastatin  N=15  Placebo (olive oil) + lovastatin placebo | Non-CVD Medications: No  Dietary Intervention(s): diet low in cholesterol and saturated fat (American Heart Association step I diet)  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Howe  199430 | N screened: NR  N included/randomized: 61  Age: 55  %female: 44.6  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Uncomplicated essential hypertension controlled by ACE inhibitor monnotherapy  Exclusion Criteria: unstable heart, renal or liver disease, DBP >105mmHg, consumed more than 20 cigarettes or 40mg of alcohol per day, exercised erratically, institutionalized, or have no control over the preparation of their food  Brief Description: Uncomplicated essential hypertension controlled by ACE inhibitor monnotherapy | Study Design: Parallel RCT  Region: Australia/New Zealand  Setting: Primary care  Industry Funded: Unclear  Treatment Duration supplement(s): 42  Treatment DurationCVD Drug(s): 42  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Captopril  Drug Category: RAAS Antagonist: ACEI  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 28  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 5000mg | N1 = 28  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): low/vs/normal sodium diet  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Isley 200731 | N screened: 100  N included/randomized: 36  Age: 49.93  %female: 31  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs: NR  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: Men and postmenopausal or surgically sterile women ages 21 to 70 years were studied; necessary for fasting serum triglyceride levels to be between 150 and 500 mg/dL; A normal chemistry screen was required to exclude secondary hypertriglyceridemia. HDL-C had to be  40 mg/dL for men and  50 mg/dL for women. LDL-C inclusion criteria were based on 1993 National Cholesterol Education Program guidelines:  130mg/dL with CHD;  160mg/dL with two or more risk factors; and  190 mg/dL with one risk factor  Exclusion Criteria: Subjects with diabetes mellitus, peptic ulcer disease, gouty arthritis, or hyperuricemia; or known hepatic, renal, autoimmune, or gastrointestinal diseases; taking warfarin, chronic nonsteroidal anti-inflammatory agents, or any medication known to affect lipid metabolism  Brief Description: patients with atherogenic dyslipidemia | Study Design: Parallel RCT  Region: NR, likely North America  Setting: NR  Industry Funded: No  Treatment Duration supplement(s): 135  Treatment DurationCVD Drug(s): 90  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 325mg  Reason for taking CVD drug(s): cardiovascular indication  +/-  Immediate-release niacin  tablets (Rugby Laboratories, West Hempstead, NY). Patients  Administration: Oral  Mean Daily Dose: escalating dose 500-3000 mg x3 /d  Reason for taking CVD drug(s): cardiovascular indication | N: 8  Supplement(s): Omega-3 (EPA, DHA or both)  Form of Administration: Capsule/tablet  Daily Dose: 4000mg | N1 = 7  Omega-3 placebo (corn oil ethyl esters 4g/d) +- niacin placebo (Calcium gluconate USP; Roxane Laboratories,  Columbus, OH). | Non-CVD Medications: ibuprofen or acetaminophen were allowed as needed  Dietary Intervention(s): Subjects were instructed to follow a low-fat, low-cholesterol diet per the National Cholesterol Education Program  Exercise Intervention(s): maintain their usual exercise habits  Other Lifestyle Intervention(s): abstain from alcohol excess |
| Jiang  200532 | N screened: NR  N included/randomized: 12  Age: NR  %female: 0  Ethnicity:  - Caucasian (6)  - Asian (6)  Comorbidities (other than indication(s) for CVDs: NR  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: All subjects were nonsmokers and were selected on the basis of medical history, physical examination and clinical laboratory test results (including INR, platelet aggregation, creatinine, bilirubin, albumin and total protein)  Exclusion Criteria: Subjects with current or past medical conditions that might affect the pharmacokinetic or pharmacodynamic response to warfarin; not taken any medication for at least 2 weeks before commencing the study  Brief Description: healthy male subjects | Study Design: Crossover RCT  Region: NR likely Australia  Setting: Primary Care  Industry Funded: No  Treatment Duration supplement(s): 7  Treatment DurationCVD Drug(s): 1  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: 25mg – 1 dose  Reason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 12  Supplement(s): Gingko biloba  Form of Administration: Capsule/tablet  Daily Dose: 12000mg  N: 12  Supplement(s): Ginger  Form of Administration: Capsule/Tablet  Daily Dose: 3600mg | N1 = 12  No treatment | Non-CVD Medications: NA  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Jiang 200433 | N screened: NR  N included/randomized: 12  Age: NR  %female: 0  Ethnicity:  - Caucasian (8)  - Asian (4)  Comorbidities (other than indication(s) for CVDs: NR  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: All subjects were nonsmokers and were selected on the basis of medical history, physical examination, and clinical laboratory test results (including INR, platelet aggregation, creatinine, bilirubin, albumin and total protein)  Exclusion Criteria: Subjects with current or past medical conditions that might affect the pharmacokinetic or pharmacodynamic response to warfarin; had not taken any medication for at least 2 weeks before commencing the study  Brief Description: healthy male subjects | Study Design: Crossover RCT  Region: NR  Setting: NR  Industry Funded: No  Treatment Duration supplement(s): 7  Treatment DurationCVD Drug(s): 1  Duration of Followup: 3  Duration of Longest Followup: 3 | Generic Name(s): Warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: 25mg – single dose  Reason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 12  Supplement(s): Ginseng  Form of Administration: Capsule/Tablet  Daily Dose: 3000mg | N1 = 12  No treatment  N2 = 12  non-relevant supplement | Non-CVD Medications: No  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Kaul  199234 | N screened: NR  N included/randomized: 107  Age: 57.37  %female: 15  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): unstable angina 33.64%  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: patients undergoing coronary angioplasty  Exclusion Criteria: history of bleeding disorder;on oral anticoagulants;emergency angioplasty;recent MI;angioplasty of a saphenous vein bypass graft;angioplasty for restenosis;inability to perform treadmill test  Brief Description: patients undergoing coronary angioplasty | Study Design: Parallel RCT  Region: Rest of Asia  Setting: Primary care  Industry Funded: Unclear  Treatment Duration supplement(s): 180  Treatment DurationCVD Drug(s): 180  Duration of Followup: 0  Duration of Longest Followup: 180 | Generic Name(s): NR  Drug Category: Calcium channel blockers  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s):  Generic Name: ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 150 mg  Reason for taking CVD drug(s): Cardiovascular indication  Generic Name: heparin  Drug Category: anticoagulants  Mode of administration: IV  Mean daily dose: 1000 units/hour for 24 hours (max. 20,000 units) | N: 58  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 10 capsules given to patients, daily dose NR | N1 = 49  No treatment | Non-CVD Medications: NA  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Kim 201035 | N screened: NR  N included/randomized: 24  Age: 24.1  %female: 0  Ethnicity: Asian (100)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: Unclear  Inclusion Criteria: Healthy males, confirmed by physical exam and lab testing  Exclusion Criteria: Those outside 80%-120% of ideal weight  Brief Description: Healthy, adult, Korean males | Study Design: Crossover RCT  Region: East Asia  Setting: General community  Industry Funded: Yes  Treatment Duration supplement(s): single dose  Treatment DurationCVD Drug(s): Single dose  Duration of Followup: 2  Duration of Longest Followup: NA | Generic Name(s): Ticlopidine  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 250mg single dose  Reason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 12  Supplement(s):Gingko Biloba  Form of Administration: Capsule/Tablet  Daily Dose: 80mg single dose | N1 = 12  No treatment | Non-CVD Medications: None  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Lee 200836 | N screened: 200  N included/randomized: 34  Age: 63.73  %female: 44  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Hypertension, diabetes mellitus, atrial fibrillation, hyperlipidemia  CHD Risk Level: high risk for CHD  Inclusion Criteria: patients with ischemic stroke who received care between Mar 2007 and Aug 2007 in the Korean Medical Hospital, Kyung Hee University Medical Center; diagnosis of stroke was defined as an acute focal or global neurologic deficit lasting more than 24 hrs without an apparent cause other than one of vascular origin, subsequently confirmed by brain CT or MRI scan within 72 hours from onset of the symptoms; Subjects were required to have scores of 3 or more on the Glasgow Outcome Scale  Exclusion Criteria: hepatic disease (alanine,aminotransferase and aspartate >2x the upper limit of laboratory normal range); history or presence of renal insufficiency (creatinine> 1.2mg/dL);hematologic abnormalities(thrombocytopenia,low granulocyte count, anemia, hypofibrinogenemia, hemophilia, vascularpurpura, hemopathy with prolongation of bleeding time, a baseline INR above the normal range [more than 1.4]); condition liable to interfere with the absorption, metabolism,or excretion of warfarin; positive test result for hepatitis (B and C) except for vaccinated patients; positive HIV test on admission lab; taking medications such as aspirin and clopidogrel  Brief Description: patients with histories of ischemic stroke | Study Design: Parallel RCT  Region: East Asia  Setting: Primary Care  Industry Funded: No  Treatment Duration supplement(s): 14  Treatment DurationCVD Drug(s): 14  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: 3.5mg  Reason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 12  Supplement(s): Ginseng  Form of Administration: aqueous extracts  Daily Dose: 1500mg | N1 = 13  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Liu  200337 | N screened: NR  N included/randomized: 88  Age: 60  %female: 69.3  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: Mixed - all participants were hyperlipidemic and subjects with obesity, high BMI, high blood pressure or insulin resistance were not excluded  Inclusion Criteria: adults with hyperlipidemia, fasting TC > 6.2 mmol/L and/or fasting TG >1.8 mmol/L. Subjects with obesity, high BMI, high blood pressure or insulin resistance were not excluded  Exclusion Criteria: Subjects with previously known lipid changes undergoing treatment; allergy to statins; diabetes mellitus; liver or renal disease; other diseases that might influence lipid metabolism; pregnant women; articipation in another drug study during the last month; treatment with antimycotic drugs or antibiotics that might interfere with the effects of statins; other drugs that may influence lipid metabolism; cancer or other serious diseases.  Brief Description: Adults with hyperlipidemia | Study Design: Parallel RCT  Region: NR (likely Europe)  Setting:  Industry Funded: Unclear  Treatment Duration supplement(s): 84  Treatment DurationCVD Drug(s): 84  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 10gmay  Reason for taking CVD drug(s): Cardiovascular indication | N: 29  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 9.2g | N1 = 18  No treatment  N2 = 22  Low fat diet  N3 = 19  Fish oil | Non-CVD Medications: NR  Dietary Intervention(s): decrease intake of fat milk, cream, and fat cheese  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Lungershausen  199438 | N screened: NR  N included/randomized: 43  Age: 61  %female: 69  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: Unclear  Inclusion Criteria: uncomplicated essential hypertension being treated with monotherapy (b-blocker and/or diuretic)  Exclusion Criteria: history of unstable heart, renal or liver disease, or DBP exceeding 105mmHg consumed more than 20 cigarettes or 40g alcohol per day or exercised erratically  Brief Description: volunteers with uncomplicated essential hypertension controlled by monotherapy with beta-blocker or diuretic or combination of 2 | Study Design: Crossover RCT  Region: Australia/New Zealand  Setting: Other (recruited by GP)  Industry Funded: Yes  Treatment Duration supplement(s): 42  Treatment DurationCVD Drug(s): 42  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  NR  Drug Category: b-blockers  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 42  Supplement(s): Fish oils/marine oils  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 42  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): told to maintain constant diet and avoid fatty fish  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Mabuchi  200739 | N screened: NR  N included/randomized: 49  Age: 60.49  %female: 71  Ethnicity: Asian (100)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: hypercholesterolemic (above 220 mg/dL)  Exclusion Criteria: pregnant or lactating women;  patients with familial hypercholesterolemia; Patients taking other lipid-lowering drugs; patients taking antioxidants  Brief Description: Japanese hypercholesterolemic | Study Design: Parallel RCT  Region: East Asia  Setting: Not reported  Industry Funded: Yes  Treatment Duration supplement(s): 112  Treatment DurationCVD Drug(s): 112  Duration of Followup: 28  Duration of Longest Followup: 28 | Generic Name(s): atorvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 10mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 24  Supplement(s): Coenzyme Q10  Form of Administration: Capsule/Tablet  Daily Dose: 100mg | N1 = 25  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): less than 300 mg of low cholesterol diet  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Macan 200640 | N screened: 66  N included/randomized: 52  Age: 55.4  %female: 66.6  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Type II Diabetes, hypertension, hypercholesterolemia (portion NR)  CHD Risk Level: At high risk for CHD  Inclusion Criteria: participants diagnosed with deep vein thrombosis, valvular heart disease, atrial fibrillation, or those with prosthetic heart valves. 18 years or older, on warfarin therapy.  Exclusion Criteria: any significant medical conditions other than those mentioned, such as the presence of a terminal disease that could shorten the lifespan of the patient (e.g. cancer), a mental condition rendering the subject unable to understand the nature, scope, and possible consequences of the study, a history of hypersensitivity to garlic or study medication, the presence of anemia (<32 mg %) thrombocytopenia (platelets <75,000/mm3), current drug abuse, active bleeding, uncontrolled hypertension, prior treatment with garlic or any related products within 3 months, and treatment with any investigational drugs within 30 days prior to signing the consent.  Brief Description: adults on warfarin therapy diagnosed with deep vein thrombosis, valvular heart disease, atrial fibrillation, or those with prosthetic heart valves | Study Design: Parallel RCT  Region: NR (likely North America)  Setting: Not reported  Industry Funded: No  Treatment Duration supplement(s): 84  Treatment DurationCVD Drug(s): 84  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Warfarin  Drug Category: Anticoagulants  Mode of Administration: NR  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 22  Supplement(s): Garlic  Form of Administration: Liquid  Daily Dose: 10ml | N1 = 26  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Maki  200841 | N screened: 98  N included/randomized: 40  Age: 58  %female: 64  Ethnicity:  - Caucasian (97)  - Asian (3)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)  Inclusion Criteria: Subjects with mixed dyslipidemia (defined as a mean fasting triglyceride level of 200 to 600 mg/dl and a non-HDL cholesterol level higher than the subject’s National Cholesterol Education Program Third Adult Treatment Panel goal); Nonpregnant, nonlactating women who were not planning on becoming pregnant during study period  Exclusion Criteria: Recent history of CV event, or revascularization procedure; presence or recent resection of an aortic aneurysm; a lipoprotein lipase impairment or deficiency,known apolipoprotein (apo) CII deficiency, or familial dysbetalipoproteinemia; significant renal (creatinine >=2.0 mg/dl), pulmonary, hepatic, biliary, or gastrointestinal disease;increased liver enzymes(1.5 times the upper limit of normal); history of pancreatitis; recent history of cancer (except nonmelanoma skin cancer); symptoms of unexplained muscle pain, tenderness or weakness, myopathy, or rhabdomyolysis; or a body mass index 40.0 kg/m2;poorly controlled hypertension; or poorly controlled diabetes  Brief Description: Subjects with mixed dyslipidemia | Study Design: Crossover RCT  Region: North America  Setting: Speciality clinic  Industry Funded: Yes  Treatment Duration supplement(s): 42  Treatment DurationCVD Drug(s): 42  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 20mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 20  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 20  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): Therapeutic Lifestyle Changes diet  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Manuel  200442 | N screened: 32  N included/randomized: 24  Age: 51  %female: 13.7  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): T1DM  CHD Risk Level: At high risk for CHD  Inclusion Criteria: Inclusion criteria were total cholesterol > 4.9 and LDL cholesterol > 3.0 mmol/L but Triglycerides < 4.5 mmol/L) and normal blood levels of thyroxin (9.7-23.4 pmol/L)  and TSH (0.4-4.0 uU/mL).  Exclusion Criteria: NR  Brief Description: T1DM patients with high cholesterol | Study Design: Parallel RCT  Region: Europe  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 183  Treatment DurationCVD Drug(s): 183  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  Atorvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 20mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 11  Supplement(s): Vitamin E  Form of Administration: Capsule/tablet  Daily Dose: 750IU | N1 = 11  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): standard diet for diabetes recommending 7.5 to 8.5 MJ (50% of the energy as carbohydrates, 20% as protein and 30% as fats). This diet assures a daily intake of at least 3 mg Vitamin E, 3000mg Vitamin A, 150 mg Vitamin C and 26 mg flavonoids.  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Mauro 200343 | N screened: NR  N included/randomized: 8  Age: 23  %female: 12.5  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: healthy adult volunteers aged 20 to 35 years willing to sign an informed consent document; All volunteers needed to pass a physical examination, have normal blood and urine chemistry results (SMA-20, CBC, coagulation panel, and urine analysis), a normal electrocardiogram, and, if female, a negative serum pregnancy test.  Exclusion Criteria: a history of psychiatric, cardiovascular, renal, gastrointestinal, hepatic, thyroid, neurologic, hematologic, or pulmonary disease; were on medication, had a history of alcohol or drug abuse, a hypersensitivity to digoxin or herbal medications, or a history of chronic smoking or had smoked within the past year.  Brief Description: young healthy adults | Study Design: Crossover RCT  Region: North America  Setting: Primary Care  Industry Funded: Unclear  Treatment Duration supplement(s): 8  Treatment DurationCVD Drug(s): 1  Duration of Followup: 1.5  Duration of Longest Followup: 1.5 | Generic Name(s): Digoxin  Drug Category: Inotropics  Mode of Administration: Oral  Mean Daily Dose:0.5mg – single dose  Reason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 8  Supplement(s): Gingko Biloba  Form of Administration: Capsule/Tablet  Daily Dose: 240mg | N1 = 8  No treatment | Non-CVD Medications: Subjects not on any medications  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| McDowell  199444 | N screened: NR  N included/randomized: 24  Age: 43.8  %female: 37.5  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Type IIa hyperlipidaemia  Exclusion Criteria: Taking regular medication for angina or hypertension oxidation  Brief Description: Patients with Type IIa hyperlipidaemia | Study Design: Parallel RCT  Region: Europe  Setting: Primary care  Industry Funded: Unclear  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 28  Duration of Followup: 28  Duration of Longest Followup: 28 | Generic Name(s):  simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 20mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 8  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 400IU | N1 = 8  Placebo  N2 = 8  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): NR  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| McKenney 200645 | N screened: NR  N included/randomized: 24  Age: 30  %female: 16.7  Ethnicity:  - Caucasian (16.7)  - Hispanic (83.3)  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: healthy male or female volunteers, aged 18 to 55 years and within 15% of ideal weight according to the 1983 Metropolitan Life Insurance Tables; nonsmokers for at least 3 months; Female subjects were required to be past menopause by more than 2 years, sexually abstinent, or using an acceptable method of birth control.  Exclusion Criteria: Persons with a history of hypersensitivity or idiosyncratic reaction to HMG-CoA reductase inhibitors or lipid-regulating agents, or allergy or sensitivity to fish; Persons who had used drugs or substances known to be strong inhibitors or inducers of CYP enzymes within 10 days (inhibitors) or 28 days (inducers) of the first dose  Brief Description: healthy adults | Study Design: Crossover RCT  Region: NR, likely North America  Setting:  Research Unit  Industry Funded: Yes  Treatment Duration supplement(s): 14  Treatment DurationCVD Drug(s): 14  Duration of Followup: 1  Duration of Longest Followup: 1 | Generic Name(s): Simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 80mg  Reason for taking CVD drug(s): exploratory analysis of the effects of P-OM3 on blood coagulation and/or platelet aggregation | N: 24  Supplement(s): Omega-3 (EPA, DHA or both)  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 24  No treatment | Non-CVD Medications: hormonal contraceptives; hormone replacement therapy allowed (portion NR)  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Meyer  200746 | N screened: NR  N included/randomized: 45  Age: 56.66  %female: 33  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: subjects on stable statin treatment for hypercholesterolaemia (i.e. already taking statin drug for at least 3 months and expecting to continue on the same dosage during the study period) who had persistent hypertriglyceridaemia (greater than 1.6 mmol/L).  Exclusion Criteria: NR  Brief Description: subjects on stable statin treatment for hypercholesterolaemia (i.e. already taking statin drug for at least 3 months | Study Design: Parallel RCT  Region: Australia/New Zealand  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 183  Treatment DurationCVD Drug(s): 183  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  19 pts were taking simvastatin, 13 atorvastatin, 4 pravastatin, 2 cerivastatin and 2 luvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 30  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg or 8000mg | N1 = 15  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Micheletta  200447 | N screened: NA  N included/randomized: 16  Age: 60.9  %female: 35  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At high risk for CHD  Inclusion Criteria: patients with carotid atherosclerosis having a lumen stenosis >70% and eligible for carotid endarterectomy  Exclusion Criteria: acute and chronic liver disease, cancer, malabsorption syndrome, prior stomach surgery, renal failure, and the use of any supplements containing vitamin E, vitamin C, carotenoids, or iron in the 30 days before the study.  Brief Description: patients with carotid atherosclerosis | Study Design: Parallel RCT  Region: Europe  Setting: Not reported  Industry Funded: Yes  Treatment Duration supplement(s): 42  Treatment DurationCVD Drug(s): 42  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  ASA or ticlopidin  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 8  Supplement(s): Vitamin E  Form of Administration: Capsule/tablet  Daily Dose: 900mg | N1 = 8  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Miyamoto  200448 | N screened: NR  N included/randomized: 40  Age: 60.9  %female: 35  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): NR  CHD Risk Level: At high risk for CHD  Inclusion Criteria: patients with coronary spastic angina, in whom spontaneous angina occurred at rest.  Exclusion Criteria: NR  Brief Description: Patients with Coronary spastic angina | Study Design: Parallel RCT  Region: East Asia  Setting: Not reported  Industry Funded: No  Treatment Duration supplement(s): 30  Treatment DurationCVD Drug(s): 30  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  Diltiazem  Drug Category: Calcium channel blockers  Mode of Administration: Oral  Mean Daily Dose: 100 OR 200 mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 20  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 400mg | N1 = 20  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Mohammed Abdul 200849 | N screened: 23  N included/randomized: 16  Age: 23  %female: 0  Ethnicity:  - Caucasian (58.3)  - Asian, including 3 Indians (41.7)  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: nonsmoking, not taking any medicines including herbal/vitamin supplements for at least 2 weeks and aged 18-34 years  Exclusion Criteria: any medical condition that could alter warfarin effects, including any clotting disorders, hepatic dysfunction or platelet dysfunction  Brief Description: healthy males | Study Design: Crossover RCT  Region: Australia/New Zealand  Setting: Primary Care  Industry Funded: No  Treatment Duration supplement(s): 21  Treatment DurationCVD Drug(s): 1  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: 25mg – single dose  Reason for taking CVD drug(s): pharmacokinetics  and pharmacodynamics | N: 4  Supplement(s): Garlic  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 4  No treatment  N2 = 4  non-relevant supplement  N3 = 4  Intervention3: non-relevant supplement | Non-CVD Medications: hormonal contraceptives; hormone replacement therapy allowed (portion NR)  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Motoyama  199850 | N screened: NR  N included/randomized: 60  Age: 60.3  %female: 49  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At high risk for CHD  Inclusion Criteria: Patients with coronary spastic angina in whom spontaneous angina occurred at rest  Exclusion Criteria: NR  Brief Description: Patients with angina | Study Design: Parallel RCT  Region: East Asia  Setting: Not reported  Industry Funded: No  Treatment Duration supplement(s): NR  Treatment DurationCVD Drug(s): NR  Duration of Followup: 30  Duration of Longest Followup: NR | Generic Name(s): NR  Diltiazem  Drug Category: Calcium channel blockers  Mode of Administration: Oral  Mean Daily Dose: 200mg  Reason for taking CVD drug(s): Cardiovascular indication | Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 300mg | Placebo (not described) | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Mueller 199151 | N screened: NR  N included/randomized: 12  Age: 29.67  %female: 41.7  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: healthy adult volunteers who provided informed consent  Exclusion Criteria: Pregnant women, anyone with a known allergy to aspirin or fish, and those taking aspirin, NSAIDs, or oral anticoagulants for a concurrent medical condition; Subjects with known platelet or coagulation disorders and subjects with thrombocytopenia, defined as a platelet count of less than 150,000/mm3 at baseline; those receiving ethanol  Brief Description: healthy adults | Study Design: Parallel RCT  Region: NR  Setting: NR  Industry Funded: Unclear  Treatment Duration supplement(s): 21  Treatment DurationCVD Drug(s): 1  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 325mg - single dose  Reason for taking CVD drug(s): bleeding-time changes associated with aspirin in normal volunteers who ingest omega-3s | N: 6  Supplement(s): Omega-3 (EPA, DHA or both)  Form of Administration: Capsule/tablet  Daily Dose: 8000mg | N1 = 6  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): subjects asked not to change diet  Exercise Intervention(s): subjects asked not to change exercise  Other Lifestyle Intervention(s): subjects asked not to change lifestyle |
| Napoli  199852 | N screened: NR  N included/randomized: 220  Age: 37.2  %female: 36  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: hypercholesterolemia and normal concentrations of triglycerides,  Exclusion Criteria: evidence of renal, liver, or endocrine diseases, type I, IIb, III, IV, V, hyperlipoproteinemia, recent MI or apoplexy (<4 months), unstable angina pectoris, surgery within the previous 4 months, severe or mild heart failure, DM or fasting glycemia (blood glucose >150mg/dl), chronic pancreatitis, porphyria, lupus erythematosus, alcoholism, patients receiving active treatment with fish oil preparations, corticosteroid, estrogens, androgens, quinidine, coumarinic derivatives, theophylline, barbituates, aluminum salts, laxatives, thiazitic diuretics and other hypolipidemic drugs and any who were hypersensitive to drugs, potentially pregnant, or breast feeding  Brief Description: hypercholesterolemic patients with normal concentrations of triglycerides | Study Design: Parallel RCT  Region: Europe  Setting: Primary care  Industry Funded: Yes  Treatment Duration supplement(s): 84  Treatment DurationCVD Drug(s): 84  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Pravastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 20-40mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 60  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 100mg | N1 = 52  no treatment  N2 = 52  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): American Heart Association Step I diet  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Neil (2010)53 | N screened: NR  N included/randomized:  Age: 64 (SD 11.5)  %female: 41.6  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs  CHD Risk Level: at high risk of CHD  Inclusion Criteria: Type 2 diabetes for at least 3 months; 18 years of age or older; no known CVD events; not thought by their general practitioner to be at high enough CVD risk to require immediate lipid-lowering therapy  Exclusion Criteria: Taking lipid lowering therapy; plasma triglycerides > 8 mmol/L; impaired hepatic function (ALT > 2 times upper limit of normal range); uncontrolled diabetes (HbA1c > 10%); uncontrolled hypertension (bp > 160/100 mm Hg); elevated creatine kinase (> 3 times upper limit of normal)  Brief Description: Patients with type 2 diabetes and no known CVD events. | Study Design: Parallel RCT  Region: NR  Setting: primary care  Industry Funded: Yes (funded by Pfizer)  Treatment Duration supplement(s): 120 days  Treatment DurationCVD Drug(s): similar to dietary treatment  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Lipitor/ atorvastatin  Drug Category: Antilipidemic (HMG Co-A Reductase Inhibitor)  Mode of Administration: Oral  Mean Daily Dose: 20 mg/d  Reason for taking CVD drug(s): cardiovascular indication | N: 163  Supplement(s): omega-3 fatty acids  Form of Administration: Capsule/Tablet  Daily Dose: 2 g/day | N1 = 169  no treatment  N2 = None | Non-CVD Medications: NR  Dietary Intervention(s): None  Exercise Intervention(s):  None  Other Lifestyle Intervention(s): None  **Note:** This study has four groups (double placebo; atorvastatin alone; omega-3 alone; and atorvastatin + omega-3. Only the atorvastatin alone and atorvastatin+omega-3 groups have been extracted. |
| Nordoy 200054 | N screened: NR  N included/randomized: 41  Age: 46.75  %female: 29.2  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Type II diabetes (2)  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: combined hyperlipemia  Exclusion Criteria: NR  Brief Description: patients with combined hyperlipemia | Study Design: Parallel RCT  Region: Europe  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 35  Treatment DurationCVD Drug(s): 35  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  Drug Category:  Mode of Administration: Oral  Mean Daily Dose:  Reason for taking CVD drug(s): Cardiovascular indication | N: 21  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 4000mg | N1 = 20  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Nordøy 200355 | N screened: NR  N included/randomized: 42  Age: 49.8  %female: 28.5  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Type II Diabetes (2)  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: patients with hyperlipemia  Exclusion Criteria: NR  Brief Description: patients with hyperlipemia | Design: Parallel RCT  Region: Europe  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 35  Treatment DurationCVD Drug(s): 35  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): atorvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: 10mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 22  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 2g | N1 = 20  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): given dietary advice by a clinical dietician to adjust their macronutrient intake to comprise 30% (or less) of energy from fat, with no more than 10% of saturated fat, 55-60% from carbohydrate (preferably complex types) and 10-15% of energy from protein.  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Paolisso  199556 | N screened: NR  N included/randomized: 30  Age: 73.8  %female: 40  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): obese  CHD Risk Level: At high risk for CHD  Inclusion Criteria: NR  Exclusion Criteria: NR  Brief Description: elderly patients with CHD | Study Design: Crossover RCT  Region: NR  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 120  Treatment DurationCVD Drug(s): 120  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  nifedipine  Drug Category: Calcium channel blockers  Mode of Administration: Oral  Mean Daily Dose: 88mg  Reason for taking CVD drug(s): Cardiovascular indication | N: NR  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 900mg | N1 = NR  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Paolisso  199257 | N screened: NR  N included/randomized: 18  Age: 64  %female: 50  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: hypertensive patients receiving long term (>1 year) thiazide treatment, (benign essential hypertension)  Exclusion Criteria: renal impairment, papilloedema, family history of diabetes or drug use known to interfere with glucose metabolism for at least 4 weeks.  Brief Description: hypertensive patients receiving thiazide treatment | Study Design: Parallel RCT  Region: NR (likely Europe)  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 56  Treatment DurationCVD Drug(s): 56  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  hydrochlorthiazide  Drug Category: Diuretic: Thiazide/Thiazide-like  Mode of Administration: Oral  Mean Daily Dose: 25mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 9  Supplement(s): Magnesium  Form of Administration: Capsule/Tablet  Daily Dose: 4500mg | N1 = 9  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Playford  200358 | N screened: NR  N included/randomized: 40  Age: 53.1  %female: 30  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At high risk for CHD  Inclusion Criteria: Patients with type 2 diabetes and dyslipidaenua (fasting triglycerdie > 1.8mmol/l or HDL-cholesterol < 1.0 mmol/l, totalcholesterol < 6.5 mmol/l, total cholesterol/HDL-cholesterol ratio >4  Exclusion Criteria: age > 75 years, BMI > 40kg/m2, history of CV event, insulin therapy, smloking, macroalbuminuria, creatinemia (> 150micromol/l), abnormal liver or muscle enzymes, use of antioxidants and lpid-regulators, hypertension (>160/90 mmHg), habitual alcohol intake > 3 standard drinks or treatment with angiotensin-converting-enzyme inhibitors and calcium antagonists.  Brief Description: Diabetic subjects with dyslipidaemia | Study Design: Parallel RCT  Region: Australia/New Zealand  Setting: Not reported  Industry Funded: No  Treatment Duration supplement(s): 84  Treatment DurationCVD Drug(s): 84  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): NR  Fenofibrate  Drug Category: Antilipidemic: Fibrate  Mode of Administration: Oral  Mean Daily Dose: 200mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 20  Supplement(s): Coenzyme Q10  Form of Administration: NR  Daily Dose: 200mg | N1 = 20  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): patients were on an isocalroic fat-modified diet for the 6 week run-in period  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Reyes 198459 | N screened: NR  N included/randomized: 21  Age: 56.7  %female: 80.9  Ethnicity:  - Caucasian (100)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: supine diastolic arterial pressures of 100 to 140 mmHg, recorded on at least two occasions separated by 7 days preceding the onset of therapy  Exclusion Criteria: patients with one or more of the following: i) secondary or renal hypertension; ii) congestive cardiac failure; iii)a history or clinical evidence of cerebrovascular impairment, including retinal haemorrages; iv) evidence of renal impairment defined as a serum creatinine level of more than 1.5 mg/dl v) hyper- or hypokalemia, arbitrarily defined by limits of 5.5 and 3.5 mol/l with a history or clinical evidence of gout vii) a history or clinical evidence of hepatic insufficiency viii) coronary insufficiancy ix)diabetes mellitus x) rheumatic conditions requiring drug therapy xi) any severe systemic disease likely to interfere with objectives of the study xii) pregnant women xiii) lactating mothers xiv) patients considered uncooperative in terms of compliance.  Brief Description: Caucasian ambulant patients with moderate to severe uncomplicated hypertension | Study Design: Parallel RCT  Region: NR (likely Africa)  Setting: NR  Industry Funded: Unclear  Treatment Duration supplement(s): 21  Treatment DurationCVD Drug(s): 21  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): hydrochlorothiazide  Drug Category: Diuretic: Thiazide/Thiazide-like  Mode of Administration: Oral  Mean Daily Dose:50mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 13  Supplement(s): Magnesium  Form of Administration: Capsule/Tablet  Daily Dose: 15.78 mmol MgCl2 | N1 = 8  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Roth 200960 | N screened: 596  N included/randomized: 167  Age: 52.04  %female: 73.6  Ethnicity:  - Caucasian (88.6)  - African-American (1.8)  - Hispanic (7.2)  - Other, not specified (6.6)  Comorbidities (other than indication(s) for CVDs): DM, high BMI  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Hypertriglyceridemic men and women (fasting TG </=500 - </= 1300 mg/dL) aged 18-79 years, with BMI >/= 25 kg/m2 and </=43 kg/m2  Exclusion Criteria: use of warfarin, cyclic sex hormone tx, or other agents known to affect lipid levels during the run-in or tx, use of cyclosporine, systemic or high dose topical corticosteroids, androgens, phenytoin, isotretinoin, or thyroid hormones (except stable-dose replacement tx- 60 days prior to day 42. While on tx also excluded pts with sensitivity to seafood/fish, fibrates, EPA or DHA in addition to any history of pancreatitis, sig. renal, hepatic, biliary, or GI disease, type 1 DM, or uncontrolled type 2 DM, pregnant women, lactating, or childbearing potential; a medically approved method of contraception were also excluded  Brief Description: subjects with very high TG levels (> or =500 mg/dL) | Study Design: Parallel RCT  Region: North America  Setting: NR  Industry Funded: Yes  Treatment Duration supplement(s): 56  Treatment DurationCVD Drug(s): 56  Duration of Followup: 56  Duration of Longest Followup: 56 | Generic Name(s): fenofibrates  Drug Category: Antilipidemic: Fibrate  Mode of Administration: Oral  Mean Daily Dose:130mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 81  Supplement(s): Omega-3  Form of Administration: NR  Daily Dose: 4000mg | N1 = 82  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): a diet run in period; reinforced NCEP TLC diet during the tx period  Exercise Intervention(s): maintaining currect physical activity  Other Lifestyle Intervention(s): No |
| Sconce  200761 | N screened: NR  N included/randomized: 70  Age: NR  %female: 50  Ethnicity: Caucasian(100)  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At high risk for CHD  Inclusion Criteria: target international normalized ratio (INR) range of 2.0 to 3.0, had been taking warfarin for at least 9 months, and were defined as having unstable control  Exclusion Criteria: Those patients whose instability was deemed to be due to poor adherence to warfarin therapy, changes in concurrent medication, comorbidity, or irregular and excessive alcohol consumption  Brief Description: Patients with atrial fibrillation anticoagulated with warfarin for thromboembolic prophylaxis | Study Design: Parallel RCT  Region: Europe  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 180  Treatment DurationCVD Drug(s): 180  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): warfarin  Drug Category: anticoagulants  Mode of Administration: Oral  Mean Daily Dose: NR (various starting and ending dosages)  Reason for taking CVD drug(s): Cardiovascular indication | N: 35  Supplement(s): Vitamin K  Form of Administration: Capsule/Tablet  Daily Dose: 0.15mg | N1 = 33  Placebo  : | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Steiner  199562 | N screened: NR  N included/randomized: 100  Age: 71  %female: 58  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At high risk for CHD  Inclusion Criteria: patients aged 18 y in whom any of the following conditions were diagnosed: 1) minor stroke, a focal ischemic cerebrovascular event that results in a less-than maximal neurologic deficit within the involved vascular distribution; 2) reversible ischemic neurologic deficit (RIND), a focal ischemic cerebrovascular event producing a neurologic deficit that persists for > 24 h but < 3 wk; 3) retinal ischemic event, an acute transient or permanent impairment of visual function caused by retinal ischemia; or 4) transient ischemic attack, a focal cerebrovascular event producing a neurologic deficit that resolves completely within 24 h of its onset. focal neurologic deficit had to occur within 8 wk of enrollment into the study, they had a performance status that allowed them to spend > 50% of their waking hours out of bed, they had no known allergy or contraindication to the use of aspirin or a-tocopherol, had no history of primary or secondary hypercoagulable state, were not using anticoagulants or platelet-active drugs other than aspirin, had no disorder other than atherosclerotic cerebrovascular disease;had no evidence of intracranial hemorrhage and no concurrent medical or signicifant psychiatric disease  Exclusion Criteria: NR  Brief Description: patients with transient ischemic attacks, minor strokes, or residual ischemic neurologic deficits | Study Design: Parallel RCT  Region: NR (likely North America)  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 730  Treatment DurationCVD Drug(s): 730  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 325mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 52  Supplement(s): Vitamin E  Form of Administration: Capsule/Tablet  Daily Dose: 400IU | N1 = 48  Placebo (not described) | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Sutken  200663 | N screened: NR  N included/randomized: 22  Age: 29.5  %female: 50  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: Hyperlipidemic subjects  Exclusion Criteria:Acute illness or severe chronic disease, diabetes, hypertension, angina pectoris or previous MI or peripheral vascular disease, thyroid dysfunction, alcohol intake, smoking, hormonal treatment, lipid-lowering medication, or vitamin or iron supplementation in the last 6 months before admission.  Brief Description: Young Hyperlipidemic | Study Design: Controlled clinical trial (CCT)  Region: Middle East  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 30  Treatment DurationCVD Drug(s): 30  Duration of Followup: 30  Duration of Longest Followup: NR | Generic Name(s): Gemfibrozil  Drug Category: Antilipidemic: Fibrate  Mode of Administration: Oral  Mean Daily Dose: 1200 mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 12  Supplement(s): Vitamin E  Form of Administration: NR  Daily Dose: 600 mg | N1 = 10  No treatment  N2 = 12  Vitamin E | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Sutken 200663 | N screened: NR  N included/randomized: 45  Age: 71.5  %female: 46.7  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD 90-1 risk factors)  Inclusion Criteria: Hyperlipidemic subjects  Exclusion Criteria: Acute illness or severe chronic disease, diabetes, hypertension, angina pectoris or previous MI or peripheral vascular disease, thyroid dysfunction, alcohol intake, smoking, hormonal treatment, lipid-lowering medication, or vitamin or iron supplementation in the last 6 months before admission.  Brief Description: Elderly hyperlipidemic | Study Design: Controlled Clincal Trial  Region: Middle East  Setting: Specialty Clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 30  Treatment DurationCVD Drug(s): 30  Duration of Followup: 30  Duration of Longest Followup: NR | Generic Name(s): Gemfibrozil  Drug Category: Antilipidemic: Fibrate  Mode of Administration: Oral  Mean Daily Dose: 1200 mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 20  Supplement(s): Vitamin E  Form of Administration: NR  Daily Dose: 600 mg | N1 = 23  No treatment  N2 = 22  Vitamin E | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Svaneborg 200264 | N screened: NR  N included/randomized: 14  Age: 31  %female: 0  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: healthy, nonsmoking, nonobese men  Exclusion Criteria: NR  Brief Description: healthy, nonsmoking, nonobese men | Study Design: Parallel RCT  Region: NR (likely Europe)  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 14  Treatment DurationCVD Drug(s): NA  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Parenteral  Mean Daily Dose: 100mg  Reason for taking CVD drug(s): Aim was to test platelet function with ASA & n-3s | N: 12  Supplement(s): Fish oils/marine  Form of Administration: Capsule/Tablet  Daily Dose: 10000mg | N1 = 6  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Tankanow  200365 | N screened: 11  N included/randomized: 11  Age: 28  %female: 50  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs: No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: age > 18 years, serum creatinine < 1.2 mg/dL, and bilirubin < 1.5 mg/dL  Exclusion Criteria: Individuals taking concurrent scheduled medications (excluding oral contraceptives), those with significant medical histories, and smokers and pregnant females  Brief Description: Healthy subjects | Study Design: Crossover RCT  Region: North America  Setting: Primary Care  Industry Funded: Unclear  Treatment Duration supplement(s): 21  Treatment DurationCVD Drug(s): 10  Duration of Followup: 0.5  Duration of Longest Followup: 3 | Generic Name(s): Digoxin  Drug Category: Inotropics  Mode of Administration: Oral  Mean Daily Dose: 0.25mg  Reason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 8  Supplement(s): Hawthorn  Form of Administration: Capsule/Tablet  Daily Dose: 900mg | N1 = 8  No treatment | Non-CVD Medications: oral contraceptives not excluded  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Watson  199966 | N screened: NR  N included/randomized: 30  Age: 55  %female: 13  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Not reported  CHD Risk Level: At high risk for CHD  Inclusion Criteria: between 18 and 75 years of age with ischemic or idiopathic dilated cardiomyopathy  Exclusion Criteria: obstructive valvular heart disease, renal (serum creatinine >0.18 mmol/liter-1) or hepatic (serum aspartate or alanine aminotransaminase > upper limit of normal) impairment, a history of alcohol or drug abuse or an inadequate echocardiographic study, or if they were pregnant  Brief Description: between 18 and 75 years of age with ischemic or idiopathic dilated cardiomyopathy | Study Design: Crossover RCT  Region: Australia/New Zealand  Setting  Industry Funded: Unclear  Treatment Duration supplement(s): 84  Treatment DurationCVD Drug(s): 84  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ACE inhibitors (no description)  Drug Category: RAAS Antagonist: ACEI  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication  Generic Name: Furosemide  Drug Category: Diuretic: Loop  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication  Generic Name:digoxin, also hydralazine and/or nitrates  Drug Category: Inotropics  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: NR  Supplement(s): Coenzyme Q10  Form of Administration: Capsule/Tablet  Daily Dose: 99mg | N1 = NR  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Wirell  199467 | N screened: NR  N included/randomized: 40  Age: 35.4  %female: 23  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: mild to moderate essential hypertension  Exclusion Criteria: Patients treated with drugs containing magnesium, ACE-inhibitors, Ca antagonists, or potassium and magnesium sparing diuretics; s-creatinine >150 mmol L-1 or serum electrolyte disturbances (sodium and potassium) according to hospital normal values; Recent myocardial infarction less than 3 months before study start or cardiac failure class NYHA IV, AV block II or III; pregnancy, malignancies, diabetes mellitus, rheumatic diseases, collagenoses and patients unable to cooperate; DIastolic blood pressure exceeding 110 mmHg and systolic blood pressure exceeding 190 mmHg  Brief Description: Patients with mild to moderate essential hypertension | Study Design: Crossover RCT  Region: Europe  Setting: Speciality clinic  Industry Funded: Unclear  Treatment Duration supplement(s): 56  Treatment DurationCVD Drug(s): 56  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): metoprolol  Drug Category: b-blockers  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication  Generic Name(s): atenolol  Drug Category: b-blockers  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication  Generic Name(s): pindolol & propanolol  Drug Category: b-blockers  Mode of Administration: Oral  Mean Daily Dose: NR  Reason for taking CVD drug(s): Cardiovascular indication | N: 19  Supplement(s): Magnesium  Form of Administration: Powder mixed with water  Daily Dose: 365mg | N1 = 20  Placebo | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Wolf  200668 | N screened: NR  N included/randomized: 50  Age: 27.2  %female: 0  Ethnicity:  - Caucasian (98)  - Asian (2)  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: normal laboratory values, had not been taking any medication within the last 3 weeks  Exclusion Criteria: Intake of medication containing ASA, anticoagulants,NSAIDs, sulfinpyrazone, ticlopidine and lipid-lowering agents  Brief Description: healthy subjects | Study Design: Crossover RCT  Region: Europe  Setting: General community  Industry Funded: Yes  Treatment Duration supplement(s): 7  Treatment DurationCVD Drug(s): 7  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): ASA  Drug Category: Antiplatelets  Mode of Administration: Oral  Mean Daily Dose: 500mg  Reason for taking CVD drug(s): to determine the influence of EBg761 on the effects of ASA on bleeding time, coagulation parameters and platelet activity | N: 50  Supplement(s): Gingko biloba  Form of Administration: Capsule/Tablet  Daily Dose: 240mg | N1 = 50  No treatment | Non-CVD Medications: paracetamol (15) and Sinupret (4)  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Yamamoto  199569 | N screened: NR  N included/randomized: NR  Age: 59.6  %female: 22.7  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): No  CHD Risk Level: At high risk for CHD  Inclusion Criteria: variant angina, angiographically normal- appearing coronary artery after ISDM administration  Exclusion Criteria: history of MI, DM, hypertension, heart failure or hyperlipidemia  Brief Description: Participants with variant angina | Study Design: Parallel RCT  Region: East Asia  Setting: Primary care  Industry Funded: Yes  Treatment Duration supplement(s): 112  Treatment DurationCVD Drug(s): 112  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s):  diltiazem  Drug Category: Calcium channel blockers  Mode of Administration: Oral  Mean Daily Dose: 90-120mg  Reason for taking CVD drug(s): Cardiovascular indication | N: 12  Supplement(s): Omega-3  Form of Administration: Capsule/Tablet  Daily Dose: 1800mg | N1 = 10  No treatment | Non-CVD Medications: NR  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Young  200770 | N screened: NR  N included/randomized: 44  Age: 59  %female: 50  Ethnicity: NR  Comorbidities (other than indication(s) for CVDs): Type II Diabetes (5)  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: patients with self-reported myalgia who had been unable to continue taking adequate doses of statin therapy  Exclusion Criteria: acute myocardial infarction or cerebral vascular accident within 3 months, alanine aminotransferase or aspartate aminotransferase >3 times the upper level of normal, calculated glomerular filtration rate <45 ml/min, decompensated heart failure, warfarin treatment, and antioxidant vitamin supplementation.  Brief Description: patients with self-reported myalgia who had been unable to continue taking adequate doses of statin therapy | Study Design: Parallel RCT  Region:NR (likely Australia)  Setting: Not reported  Industry Funded: Unclear  Treatment Duration supplement(s): 63  Treatment DurationCVD Drug(s): 63  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): simvastatin  Drug Category: Antilipidemic: HMG Co-A Reductase Inhibitor  Mode of Administration: Oral  Mean Daily Dose: Staring 10mg, ending 40mg  Reason for taking CVD drug(s): NR | N = 22  Supplement(s): Coenzyme Q10  Form of Administration: Capsule/Tablet  Daily Dose: 200mg | N1 = 22  Placebo | Non-CVD Medications: Ezetimibe (4)  Dietary Intervention(s): No  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |
| Yuan 200471 | N screened: NR  N included/randomized: 21  Age: 27.84  %female: 55  Ethnicity:  - Caucasian (10)  - African-American (5)  - Hispanic (3)  - Asian (2)  Comorbidities (other than indication(s) for CVDs: NR  CHD Risk Level: At low risk for CHD (0-1 risk factors)  Inclusion Criteria: NR  Exclusion Criteria: NR  Brief Description: Healthy patients | Study Design: Parallel RCT  Region: North America  Setting: Primary Care  Industry Funded: No  Treatment Duration supplement(s): 28  Treatment DurationCVD Drug(s): 6  Duration of Followup: End of treatment period  Duration of Longest Followup: End of treatment period | Generic Name(s): Warfarin  Drug Category: Anticoagulants  Mode of Administration: Oral  Mean Daily Dose: 5mg  Reason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 12  Supplement(s): Ginseng  Form of Administration: Capsule/Tablet  Daily Dose: 2000mg | N1 = 8  Placebo | Non-CVD Medications: NA  Dietary Intervention(s): Patients were instructed to eat a balanced diet to maintain a consistent amount of vitamin K and to avoid drastic changes in dietary habits  Exercise Intervention(s): No  Other Lifestyle Intervention(s): No |