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: NRN included/randomized: 12 Age: 24%female: 0Ethnicity: - Caucasian (6)- Asian (6) Comorbidities (other than indication(s) for CVDs: NRCHD 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 dysfunctionBrief Description: healthy male subjects of known CYP2C9 and VKORC1 genotype | Study Design: Crossover RCTRegion: NR, likely AustraliaSetting: NRIndustry Funded: YesTreatment Duration supplement(s): 21Treatment DurationCVD Drug(s): Single doseDuration of Followup: 7Duration of Longest Followup: 7 | Generic Name(s): warfarinDrug Category: AnticoagulantsMode of Administration: Oral Mean Daily Dose: 25mg- 1 doseReason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 12Supplement(s): Echinacea Form of Administration: Capsule/TabletDaily Dose: 5100 mg | N1 = 12 No treatmentN2 = 12policosanol (non-relevant supplement) | Non-CVD Medications: NADietary Intervention(s): NoExercise Intervention(s): NoOther 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** |
| Aruna20072  | N screened: 16N included/randomized: 10 Age: 27%female: 0Ethnicity: NR Comorbidities (other than indication(s) for CVDs: NoCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: NRExclusion Criteria: subjects hypersensitive to study drugs, chronic smokers or alcoholics, and a history of gastrointestinal surgery that could interfere with absorption of study drugsBrief Description: healthy male subjects | Study Design: Crossover RCTRegion: Rest of AsiaSetting: General communityIndustry Funded: UnclearTreatment Duration supplement(s): 1Treatment DurationCVD Drug(s): 1Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): cilostazolDrug Category: Vasodilator: Nitrates/PDE-5 InhibitorsMode of Administration: OralMean Daily Dose: 150mgReason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic studyGeneric Name(s): clopidogrelDrug Category: Antiplatelets Mode of Administration: OralMean Daily Dose: 112.5mgReason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 10Supplement(s): Gingko bilobaForm of Administration: Capsule/TabletDaily Dose: 120mg single dose | N1 = 10 No treatmentN2 = 10No treatment | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Avogaro19743  | N screened: NRN included/randomized: 20Age: NR%female: NREthnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD 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 WHOExclusion Criteria: NRBrief Description: Patients suffering from hyperlipoproteinemia | Study Design: Crossover RCTRegion: EuropeSetting: Primary careIndustry Funded: UnclearTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 28Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): propranololDrug Category: b-blockersMode of Administration: OralMean Daily Dose: 20mg OR 60mgReason for taking CVD drug(s): Cardiovascular indication | N: 20Supplement(s): NiacinForm of Administration: Capsule/tabletDaily Dose: 250 mg (and non-relevant dose of 750mg/day) | N1 = 20PlaceboN2 = 20No treatmentN3 = 20Intervention3: No treatment | Non-CVD Medications: NRDietary 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): NoOther Lifestyle Intervention(s): No |
| Balestrieri19964  | N screened: NRN included/randomized: 16Age: 42.5%female: 44Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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 functionExclusion Criteria: diabetic, obeseBrief Description: Group of heterozygous FH patients on long-term treatment with simvastatin | Study Design: Crossover RCTRegion: EuropeSetting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 28Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR SimvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: range 10-40mgReason for taking CVD drug(s): Cardiovascular indication | N: 8Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/tabletDaily Dose: 5100mg | N1 = 8 Placebo | Non-CVD Medications: NADietary Intervention(s): lipid lowering diet (Step 1 AHA diet)Exercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Barbagallo19995  | N screened: NRN included/randomized: 24Age: 47.05%female: 54Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD 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 intoleranceBrief Description: Patients with essential hypertension | Study Design: Parallel RCTRegion: EuropeSetting: Primary careIndustry Funded: UnclearTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 28Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): furosemideDrug Category: Diuretic: LoopMode of Administration: OralMean Daily Dose: 25mgReason for taking CVD drug(s): Cardiovascular indication | N: 12Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 600mg | N1 = 12 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Bays20106 | N screened: 585N included/randomized: 245Age: 56.15%female: 42Ethnicity: Caucasian (89)Comorbidities (other than indication(s) for CVDs): NoCHD 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/dLExclusion 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 rhabdomyolysisBrief Description: patients with combined hyperlipidemia | Study Design: Parallel RCTRegion: North AmericaSetting: Specialty clinicIndustry Funded:YesTreatment Duration supplement(s): 112Treatment DurationCVD Drug(s): 112Duration of Followup: End of treatment periodDuration of Longest Followup: NR | Generic Name(s): atorvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 10, 20 and 40mgReason for taking CVD drug(s): Cardiovascular indication | N: 123Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose:: 4000mg | N1 = 122 Placebo plus atorvastatin | Non-CVD Medications: noneDietary Intervention(s): National Cholesterol Education Program therapeutic lifestyle changes dietExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Bays20097  | N screened: 596N included/randomized: 167Age: 52.05%female: 26.35Ethnicity:- 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 dyslipidemiaExclusion 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 contraceptionBrief Description: 18-75 years old, overweight/obese, with dyslipidemia | Study Design: Parallel RCTRegion: North AmericaSetting: Not reportedIndustry Funded: YesTreatment Durationsupplement(s): 56Treatment DurationCVD Drug(s): 56Duration of Followup: 56Duration of Longest Followup: End of treatment period | Generic Name(s): fenofibrateDrug Category: Antilipidemic: FibrateMode of Administration: OralMean Daily Dose: 130mgReason for taking CVD drug(s): Cardiovascular indication | N: 75Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 75 Placebo | Non-CVD Medications: NRDietary Intervention(s): low saturated fat NCEP Therapeutic Lifestyle Changes (TLC) dietExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Bender19988 | N screened: NRN included/randomized: 16Age: 53.5%female: 54.5Ethnicity:- African-American (9)- Hispanic (91)Comorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: UnclearInclusion 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 contraceptionBrief Description:Patients receiving chronic warfarin therapy for indications requiring oral anticoagulation | Study Design: Parallel RCTRegion: North AmericaSetting:Industry Funded: UnclearTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 28Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): warfarinDrug Category: AnticoagulantsMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 3000 or 6000mg | Placebo (matching; R.P. Schering PharmaceuticalsCorporation) | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Bordia19989  | N screened: NRN included/randomized: 60Age: NR%female: NREthnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: At high risk for CHDInclusion Criteria: Patients with CAD and with old healed MI (> 6 months) with or without angina.Exclusion Criteria: NRBrief Description: Patients with CAD | Study Design: Controlled clinical trial (CCT)Region: EuropeSetting: Not reportedIndustry Funded: NoTreatment Duration supplement(s): 90Treatment DurationCVD Drug(s): UnclearDuration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR NitratesDrug Category: Vasodilator: Nitrates/PDE-5 InhibitorsMode of Administration: NRMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 30Supplement(s): GarlicForm of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 30 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Budoff 200410  | N screened: NRN included/randomized: 23Age: 59.6%female: 26Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At high risk for CHDInclusion 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 supplementBrief Description: patients with known coronary artery disease or high risk for coronary artery disease | Study Design: Parallel RCTRegion: NR, likely North AmericaSetting: NRIndustry Funded: UnclearTreatment Duration supplement(s): 365Treatment DurationCVD Drug(s): 365Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): Statin Drug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: NRMean Daily Dose: Range of 10-40mgReason for taking CVD drug(s): Cardiovascular indication | N: 9Supplement(s): GarlicForm of Administration: LiquidDaily Dose: 4 ml | N1 = 10 PlaceboN2 = NANA | Non-CVD Medications: NRDietary Intervention(s): All participants were educated on a low-cholesterol diet at entry to the study by the nurse coordinatorExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Caso200711  | N screened: NRN included/randomized: 32Age: 60.63%female: 47Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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 anticoagulantsBrief Description: patients using statins with myopathic pain | Study Design: Parallel RCTRegion: North AmericaSetting: Speciality clinicIndustry Funded: NoTreatment Duration supplement(s): 30Treatment DurationCVD Drug(s): 30Duration of Followup: End of treatment periodDuration 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 InhibitorMode of Administration: OralMean Daily Dose: varying doses for all patientsReason for taking CVD drug(s): Cardiovascular indication | N: 18Supplement(s): Coenzyme Q10Form of Administration: Capsule/TabletDaily Dose: 100mg | N1 = 14 Vitamin E, 400IU | Non-CVD Medications: nonsteroidal anti-inflammatory drugs taken by 9 patientsDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): patients were already following Adult Treatment Panel III/National Cholesterol Education Program guidelines |
| Chan200212  | N screened: 52N included/randomized: 52Age: 53.23%female: 0Ethnicity: NRComorbidities (other than indication(s) for CVDs): obeseCHD 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 dietExclusion Criteria: diabetes;apolipoprotein E2/D2 genotype;macroproteinuria;creatinaemia(>120umolL-1);hypothyroidism;abnormal liver and muscle enzymes; consumed fish oil supplements; more than 30g alcoholBrief Description: viscerally obese men | Study Design: Parallel RCTRegion: NRSetting: Not reportedIndustry Funded: YesTreatment Duration supplement(s): 42Treatment DurationCVD Drug(s): 42Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR AtorvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 40mgReason for taking CVD drug(s): Cardiovascular indication | N: Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 4000mg | N1 =  PlaceboN2 = fish oil + atorvastatin placebo | Non-CVD Medications: NADietary Intervention(s): isocaloric dietExercise Intervention(s): keep their physical activity constantOther Lifestyle Intervention(s): No |
| d'Arcangues200413  | N screened: NRN included/randomized: 9297Age: NR%female: NREthnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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, previousimmediate 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 RCTRegion: Multiple (East Asia, Central & South America)Setting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 10Treatment DurationCVD Drug(s): 10Duration of Followup: 360Duration of Longest Followup: 360 | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 80mgReason for taking CVD drug(s): Norplant-induced prolonged vaginal bleeding | N: 120Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 200mg | N1 = 122 No treatmentN2 = 123Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Davidson200714  | N screened: 690N included/randomized: 256Age: 59.8%female: 42.5Ethnicity: NR- Caucasian (95.7)- African-American (2)- Hispanic (1.6)- Asian (1.2)Comorbidities (other than indication(s) for CVDs): NoCHD 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 ATPExclusion 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 ULNBrief Description: patients with persistent hypertriglyceridemia despite statin therapy | Study Design: Parallel RCTRegion: North AmericaSetting: Speciality clinicIndustry Funded: YesTreatment Duration supplement(s): 56Treatment DurationCVD Drug(s): 112Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s):simvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 40mgReason for taking CVD drug(s): Cardiovascular indication | N: 123Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 133 Placebo | Non-CVD Medications: NADietary Intervention(s): NCEP Therapeutic Lifestyle Changes dietExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Davidson199715  | N screened: 46N included/randomized: 30Age: NR%female: NREthnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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: NRBrief Description: Hyperlipidemic subjects | Study Design: Parallel RCTRegion: NRSetting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 84Treatment DurationCVD Drug(s): 84Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR SimvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 10mgReason for taking CVD drug(s): Cardiovascular indication | N: 10Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 10000mg | N1 = 10 No treatmentN2 = 9Fish oil  | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| De, Caterina200216  | N screened: NRN included/randomized: 43Age: 63.1%female: 51Ethnicity: NRComorbidities (other than indication(s) for CVDs): diabetes (19%)CHD Risk Level: At high risk for CHDInclusion Criteria: hypercholesterolemic subjects (Fredrickson IIa or IIb) with serum cholesterol 200 mg/dL and proven vascular (coronary, carotid, or peripheral arterial) disease.Exclusion Criteria: NRBrief Description: hypercholesterolemic subjects with proven vascular disease | Study Design: Crossover RCTTreatment Duration: 30Region: NRSetting: Not reportedIndustry Funded: YesTreatment Duration supplement(s): 30Treatment DurationCVD Drug(s): 30Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR simvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 10mgReason for taking CVD drug(s): Cardiovascular indication | N: 21Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 600mg | N1 = 22 No treatment | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Dehmer198817 | N screened: 149N included/randomized: 90Age: 56%female: 0Ethnicity: NRComorbidities (other than indication(s) for CVDs): diabetes 28% in control groupl; 21% in treatment groupCHD Risk Level: At moderate/moderately high risk for CHD (2+ risk factors)Inclusion Criteria: male patients referred to laboratory for angioplastyExclusion 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 RCTRegion: North AmericaSetting: Speciality clinicIndustry Funded: NoTreatment Duration supplement(s): 187Treatment DurationCVD Drug(s): 187Duration of Followup: 270,360Duration of Longest Followup: 360 | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 325mgReason for taking CVD drug(s): Cardiovascular indicationGeneric Name: dipyridamoleDrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 225mgReason for taking CVD drug(s): Cardiovascular indicationGeneric Name: NRDrug Category: Calcium channel blockersMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 43Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 3200mg | N1 = 39No treatment | Non-CVD Medications: NADietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Desideri200318  | N screened: 67N included/randomized: 67Age: 47.7%female: 42Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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 electrocardiogramExclusion 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 RCTRegion: EuropeSetting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 180Treatment DurationCVD Drug(s): 180Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR SimvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 40mgReason for taking CVD drug(s):Generic Name: NR BezafibrateDrug Category: Antilipidemic: FibrateMode of Administration: OralMean Daily Dose: 800mgReason for taking CVD drug(s): Cardiovascular indication | N: 31Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 400IU | N1 = 19 No treatmentN2 = 17No treatment | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Di Spirito 200819  | N screened: 50N included/randomized: 50Age: 35%female: 20Ethnicity: - Caucasian (98)- African-American (2)Comorbidities (other than indication(s) for CVDs: NoCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: NRExclusion Criteria: Women who were pregnant or lactating or who were planning a pregnancy; Individuals with a history of hypersensitivity or allergy to study medicationsBrief Description: healthy non-smoking men and women within 15% of ideal body weight | Study Design: Crossover RCTRegion: North AmericaSetting: Research FacilityIndustry Funded: YesTreatment Duration supplement(s): 14Treatment DurationCVD Drug(s): 14Duration of Followup: 1Duration of Longest Followup: 1 | Generic Name(s): atorvastatinDrug Category: Antilipidemic: HMG Co-A Reductase Inhibitor Mode of Administration: OralMean Daily Dose: 80mgReason for taking CVD drug(s): pharmacokinetics of atorvastatin and P-OM3 | N: 50Supplement(s): Omega-3 (EPA, DHA or both)Form of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 50 No treatment | Non-CVD Medications: hormonal contraceptives (portion NR)Dietary Intervention(s): No Exercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Duffy200120  | N screened: NRN included/randomized: 29Age: 28.7%female: 54Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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 supplementsBrief Description: young patients with hypercholesterolaemia | Study Design: Parallel RCTRegion: NR (likely Australia)Setting: Not reportedIndustry Funded: NoTreatment Duration supplement(s): 180Treatment DurationCVD Drug(s): 180Duration of Followup: End of treatment periodDuration of Longest Followup: : End of treatment period | Generic Name(s): NA simvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: starting dose 10mg; ending dose 40mgReason for taking CVD drug(s): Cardiovascular indication |  N: 6Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 1000 IU | N1 = 7 Placebo N2 = 7No treatmentN3 = 6Intervention3: Vitamin E  | Non-CVD Medications: estrogen-based oral contraceptives (portion of population)Dietary Intervention(s): dietary advice and information sheets on cholesterol lowering dietsExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Eritsland199621  | N screened: NRN included/randomized: 291Age: 60.49%female: 12.5Ethnicity: NRComorbidities (other than indication(s) for CVDs): DiabetesCHD Risk Level: At high risk for CHDInclusion 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 reasonsBrief Description: Subjects undergoing coronary artery bypass grafting without surgery | Study Design: Parallel RCTRegion: EuropeSetting: Specialty ClinicIndustry Funded: UnclearTreatment Duration supplement(s): 365Treatment DurationCVD Drug(s): 365Duration of Followup: 365Duration of Longest Followup: 365 | Generic Name(s):ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 300mgReason for taking CVD drug(s): | N: 143 Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 148 No treatment | Non-CVD Medications: NRDietary 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): NoOther Lifestyle Intervention(s): No |
| Eritsland199621  | N screened: NRN included/randomized: 319Age: 59.54%female: 13.8Ethnicity: NRComorbidities (other than indication(s) for CVDs): DiabetesCHD Risk Level: At high risk for CHDInclusion 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 reasonsBrief Description: Subjects undergoing coronary artery bypass grafting without surgery | Study Design: Parallel RCTRegion: EuropeSetting: Specialty ClinicIndustry Funded: UnclearTreatment Duration supplement(s): 365Treatment DurationCVD Drug(s): 365Duration of Followup: 365Duration of Longest Followup: 365 | Generic Name(s):warfarinDrug Category: AnticoagulantsMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 174Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 145 No treatment | Non-CVD Medications: NRDietary 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): NoOther Lifestyle Intervention(s): No |
| Ferraro200922  | N screened: NRN included/randomized: 30Age: 45%female: 36.6Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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 includedExclusion 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 RCTRegion: EuropeSetting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 180Treatment DurationCVD Drug(s): 180Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ramiprilDrug Category: RAAS Antagonist: ACEIMode of Administration: OralMean Daily Dose: 10mgReason for taking CVD drug(s): IgA nephropathy | N: 15Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily 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): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Gardner200723  | N screened: 188N included/randomized: 67Age: 68.5%female: 40Ethnicity:- Caucasian (75)- African-American (5)- Hispanic (13)- Asian (7)Comorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At high risk for CHDInclusion 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: NRBrief 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 RCTRegion:NR (likely North America)Setting: Not reportedIndustry Funded: YesTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 42Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 325mgReason for taking CVD drug(s): Cardiovascular indication | N: 29Supplement(s): Gingko bilobaForm of Administration: Capsule/TabletDaily Dose: 300mg | N1 = 26 Placebo | Non-CVD Medications: NADietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Garg199524  | N screened: 98N included/randomized: 62Age: 54.19%female: 29.6Ethnicity: NRComorbidities (other than indication(s) for CVDs): NRCHD Risk Level: At high risk for CHDInclusion 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 arteryExclusion 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 RCTRegion: Rest of AsiaSetting: Primary careIndustry Funded: UnclearTreatment Duration supplement(s): 7Treatment DurationCVD Drug(s): UnclearDuration of Followup: 14Duration of Longest Followup: 14 | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 29Supplement(s): Gingko bilobaForm of Administration: Capsule/TabletDaily Dose: 240mg | N1 = 26 Placebo | Non-CVD Medications: antibiotics and short-term glucocorticoidsDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Glynn200725  | N screened: 453787N included/randomized: 65169Age: NR%female: 100Ethnicity:- 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 anticoagulantsBrief Description: Healthy women not currently using anticoagulants | Study Design: Parallel RCTRegion: North AmericaSetting: General communityIndustry Funded: UnclearTreatment Duration supplement(s): 3650Treatment DurationCVD Drug(s): 3650Duration of Followup: 3650Duration of Longest Followup: 3650 | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 100mg/every other dayReason for taking CVD drug(s): prevention | N: 19,937Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 600IU/every other day | N1 = 19,939 Placebo | Non-CVD Medications: Hormone therapy (30%)Dietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Gosai200826  | N screened: NRN included/randomized: 48Age: 37%female: 25Ethnicity: - Caucasian (42) - Other (arabic, african or undefined ethnicity) (6)Comorbidities (other than indication(s) for CVDs: NRCHD 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 weightExclusion Criteria: Women who were pregnant, lactating, or planning a pregnancy; individuals with a history of hypersensitivity or allergy to study medicationsBrief Description: healthy adult volunteers | Study Design: Crossover RCTRegion: NRSetting: NRIndustry Funded: YesTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 28Duration of Followup: 1Duration of Longest Followup: 1 | Generic Name(s): rosuvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 40mgReason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 48Supplement(s): Omega-3 (EPA, DHA or both)Form of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 48 No treatment | Non-CVD Medications: hormonal contraceptives (portion NR)Dietary Intervention(s): meal plans provided 4 and 9h after each dosingExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Govil 197927  | N screened: NRN included/randomized: 80Age: NR%female: 31Ethnicity: NRComorbidities (other than indication(s) for CVDs: NoCHD Risk Level: At high risk for CHDInclusion Criteria: congestive cardiac failureExclusion Criteria: renal insufficiencyBrief Description: patients of congestive cardiac failure | Study Design: Controlled Clinical TrialRegion: Rest of AsiaSetting: Primary CareIndustry Funded: UnclearTreatment Duration supplement(s): NRTreatment DurationCVD Drug(s): NRDuration of Followup: 8Duration of Longest Followup: 8 | Generic Name(s): DigoxinDrug Category: InotropicsMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s):Cardiovascular indicationGeneric Name(s): DiureticsDrug Category: Diuretic: LoopMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s):Cardiovascular indication | N: 20Supplement(s): MagnesiumForm of Administration: LiquidCapsule/Tablet Daily Dose: 396 mEq | N1 = 60No treatment | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Hajda, 201028 | N screened: NRN included/randomized: 10Age: 28.8%female: 0Ethnicity: Caucasian Comorbidities (other than indication(s) for CVDs: NoneCHD Risk Level: At low risk for CHD Inclusion Criteria: healthy male subjects (based on physical examinations, standard clinical chemistry and hematology analyses) Exclusion Criteria: NRBrief 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: EuropeSetting: UnclearIndustry Funded: YesTreatment Duration supplement(s): 21 daysTreatment DurationCVD Drug(s): 21 daysDuration of Followup: 21 daysDuration of Longest Followup: 22 days | Generic Name(s): Statins (pravastatin, or simvastatin)Mode of Administration: OralDaily Dose: 20 mgReason for taking CVD drug(s):non- Cardiovascular indicationGeneric Name(s): Drug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): non-Cardiovascular indication | N: 10Supplement(s): GarlicForm of Administration: Capsule/Tablet Daily Dose: 600 mg bid (twice daily) | N1 = 10No treatment | Non-CVD Medications: NoDietary 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): NoOther Lifestyle Intervention(s): NR |
| Hansen199329  | N screened: NRN included/randomized: 15Age: 49%female: 53.3Ethnicity: NRComorbidities (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 illnessesExclusion Criteria: peptic ulcers, gastrointestinal disorders likely to influence drug absorption, alcoholism, drug abuse, or mental illnessBrief Description: hypercholesterolemic patients within 15% of their ideal body weight | Study Design: Crossover RCTRegion: EuropeSetting: Primary careIndustry Funded: UnclearTreatment Duration supplement(s): 42Treatment DurationCVD Drug(s): 42Duration of Followup: 84Duration of Longest Followup: 84 | Generic Name(s): lovastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 40mgReason for taking CVD drug(s): Cardiovascular indication | N=15Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 6000mg | N=15Placebo (olive oil) + lovastatinN=15Placebo (olive oil) + lovastatin placebo | Non-CVD Medications: NoDietary Intervention(s): diet low in cholesterol and saturated fat (American Heart Association step I diet)Exercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Howe199430  | N screened: NRN included/randomized: 61Age: 55%female: 44.6Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: Uncomplicated essential hypertension controlled by ACE inhibitor monnotherapyExclusion 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 foodBrief Description: Uncomplicated essential hypertension controlled by ACE inhibitor monnotherapy | Study Design: Parallel RCTRegion: Australia/New ZealandSetting: Primary careIndustry Funded: UnclearTreatment Duration supplement(s): 42Treatment DurationCVD Drug(s): 42Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): CaptoprilDrug Category: RAAS Antagonist: ACEIMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 28Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 5000mg | N1 = 28Placebo | Non-CVD Medications: NRDietary Intervention(s): low/vs/normal sodium dietExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Isley 200731 | N screened: 100N included/randomized: 36Age: 49.93%female: 31Ethnicity: NRComorbidities (other than indication(s) for CVDs: NRCHD 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 fastingserum 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 factorExclusion Criteria: Subjects with diabetes mellitus, peptic ulcer disease, gouty arthritis, or hyperuricemia; or known hepatic, renal, autoimmune, or gastrointestinal diseases; taking warfarin, chronic nonsteroidalanti-inflammatory agents, or any medication known to affect lipid metabolismBrief Description: patients with atherogenic dyslipidemia | Study Design: Parallel RCTRegion: NR, likely North AmericaSetting: NRIndustry Funded: NoTreatment Duration supplement(s): 135Treatment DurationCVD Drug(s): 90Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 325mgReason for taking CVD drug(s): cardiovascular indication+/- Immediate-release niacintablets (Rugby Laboratories, West Hempstead, NY). PatientsAdministration: OralMean Daily Dose: escalating dose 500-3000 mg x3 /dReason for taking CVD drug(s): cardiovascular indication | N: 8Supplement(s): Omega-3 (EPA, DHA or both)Form of Administration: Capsule/tabletDaily Dose: 4000mg | N1 = 7Omega-3 placebo (corn oil ethyl esters 4g/d) +- niacin placebo (Calcium gluconate USP; Roxane Laboratories,Columbus, OH). | Non-CVD Medications: ibuprofen or acetaminophenwere allowed as neededDietary Intervention(s): Subjects were instructed to follow a low-fat, low-cholesterol diet per the National Cholesterol Education ProgramExercise Intervention(s): maintain their usual exercise habitsOther Lifestyle Intervention(s): abstain from alcohol excess |
| Jiang200532  | N screened: NRN included/randomized: 12Age: NR%female: 0Ethnicity: - Caucasian (6)- Asian (6)Comorbidities (other than indication(s) for CVDs: NRCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: All subjects were nonsmokers and wereselected on the basis of medical history, physical examination and clinical laboratory test results (including INR, platelet aggregation, creatinine, bilirubin, albuminand total protein)Exclusion Criteria: Subjects with current or past medical conditions that might affect the pharmacokinetic orpharmacodynamic response to warfarin; not taken any medication for at least 2 weeks before commencing thestudyBrief Description: healthy male subjects | Study Design: Crossover RCTRegion: NR likely AustraliaSetting: Primary CareIndustry Funded: NoTreatment Duration supplement(s): 7Treatment DurationCVD Drug(s): 1Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): warfarinDrug Category: AnticoagulantsMode of Administration: OralMean Daily Dose: 25mg – 1 doseReason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 12Supplement(s): Gingko bilobaForm of Administration: Capsule/tabletDaily Dose: 12000mgN: 12Supplement(s): GingerForm of Administration: Capsule/Tablet Daily Dose: 3600mg | N1 = 12 No treatment | Non-CVD Medications: NADietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Jiang 200433  | N screened: NRN included/randomized: 12Age: NR%female: 0Ethnicity: - Caucasian (8)- Asian (4)Comorbidities (other than indication(s) for CVDs: NRCHD 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 studyBrief Description: healthy male subjects | Study Design: Crossover RCTRegion: NR Setting: NR Industry Funded: No Treatment Duration supplement(s): 7Treatment DurationCVD Drug(s): 1Duration of Followup: 3Duration of Longest Followup: 3 | Generic Name(s): WarfarinDrug Category: Anticoagulants Mode of Administration: OralMean Daily Dose: 25mg – single doseReason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 12Supplement(s): GinsengForm of Administration: Capsule/Tablet Daily Dose: 3000mg | N1 = 12 No treatmentN2 = 12non-relevant supplement | Non-CVD Medications: NoDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Kaul199234  | N screened: NRN included/randomized: 107Age: 57.37%female: 15Ethnicity: NRComorbidities (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 angioplastyExclusion 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 testBrief Description: patients undergoing coronary angioplasty | Study Design: Parallel RCTRegion: Rest of AsiaSetting: Primary careIndustry Funded: UnclearTreatment Duration supplement(s): 180Treatment DurationCVD Drug(s): 180Duration of Followup: 0Duration of Longest Followup: 180 | Generic Name(s): NRDrug Category: Calcium channel blockersMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s):Generic Name: ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 150 mgReason for taking CVD drug(s): Cardiovascular indicationGeneric Name: heparinDrug Category: anticoagulantsMode of administration: IVMean daily dose: 1000 units/hour for 24 hours (max. 20,000 units) | N: 58Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 10 capsules given to patients, daily dose NR | N1 = 49No treatment | Non-CVD Medications: NADietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Kim 201035  | N screened: NRN included/randomized: 24Age: 24.1%female: 0Ethnicity: Asian (100)Comorbidities (other than indication(s) for CVDs): NoCHD Risk Level: UnclearInclusion Criteria: Healthy males, confirmed by physical exam and lab testingExclusion Criteria: Those outside 80%-120% of ideal weightBrief Description: Healthy, adult, Korean males | Study Design: Crossover RCTRegion: East AsiaSetting: General communityIndustry Funded: YesTreatment Duration supplement(s): single doseTreatment DurationCVD Drug(s): Single doseDuration of Followup: 2Duration of Longest Followup: NA | Generic Name(s): TiclopidineDrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 250mg single doseReason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 12Supplement(s):Gingko BilobaForm of Administration: Capsule/TabletDaily Dose: 80mg single dose | N1 = 12 No treatment | Non-CVD Medications: NoneDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Lee 200836  | N screened: 200N included/randomized: 34 Age: 63.73%female: 44Ethnicity: NRComorbidities (other than indication(s) for CVDs): Hypertension, diabetes mellitus, atrial fibrillation, hyperlipidemiaCHD Risk Level: high risk for CHDInclusion 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 ScaleExclusion 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 clopidogrelBrief Description: patients with histories of ischemic stroke | Study Design: Parallel RCTRegion: East AsiaSetting: Primary CareIndustry Funded: NoTreatment Duration supplement(s): 14Treatment DurationCVD Drug(s): 14Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): WarfarinDrug Category: Anticoagulants Mode of Administration: OralMean Daily Dose: 3.5mgReason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 12Supplement(s): GinsengForm of Administration: aqueous extractsDaily Dose: 1500mg | N1 = 13 No treatment | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Liu200337 | N screened: NRN included/randomized: 88Age: 60%female: 69.3Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: Mixed - all participants were hyperlipidemic and subjects with obesity, high BMI, high blood pressure or insulin resistance were not excludedInclusion 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 excludedExclusion 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 RCTRegion: NR (likely Europe)Setting:Industry Funded: UnclearTreatment Duration supplement(s): 84Treatment DurationCVD Drug(s): 84Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): simvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 10gmayReason for taking CVD drug(s): Cardiovascular indication | N: 29Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 9.2g | N1 = 18No treatmentN2 = 22Low fat dietN3 = 19Fish oil | Non-CVD Medications: NRDietary Intervention(s): decrease intake of fat milk, cream, and fat cheeseExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Lungershausen199438  | N screened: NRN included/randomized: 43Age: 61%female: 69Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: UnclearInclusion 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 erraticallyBrief Description: volunteers with uncomplicated essential hypertension controlled by monotherapy with beta-blocker or diuretic or combination of 2 | Study Design: Crossover RCTRegion: Australia/New ZealandSetting: Other (recruited by GP)Industry Funded: YesTreatment Duration supplement(s): 42Treatment DurationCVD Drug(s): 42Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR NRDrug Category: b-blockersMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 42Supplement(s): Fish oils/marine oilsForm of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 42Placebo | Non-CVD Medications: NADietary Intervention(s): told to maintain constant diet and avoid fatty fishExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Mabuchi200739  | N screened: NRN included/randomized: 49Age: 60.49%female: 71Ethnicity: Asian (100)Comorbidities (other than indication(s) for CVDs): NoCHD 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 antioxidantsBrief Description: Japanese hypercholesterolemic | Study Design: Parallel RCTRegion: East AsiaSetting: Not reportedIndustry Funded: YesTreatment Duration supplement(s): 112Treatment DurationCVD Drug(s): 112Duration of Followup: 28Duration of Longest Followup: 28 | Generic Name(s): atorvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 10mgReason for taking CVD drug(s): Cardiovascular indication | N: 24Supplement(s): Coenzyme Q10Form of Administration: Capsule/TabletDaily Dose: 100mg | N1 = 25 Placebo | Non-CVD Medications: NADietary Intervention(s): less than 300 mg of low cholesterol dietExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Macan 200640  | N screened: 66N included/randomized: 52Age: 55.4%female: 66.6Ethnicity: NRComorbidities (other than indication(s) for CVDs): Type II Diabetes, hypertension, hypercholesterolemia (portion NR)CHD Risk Level: At high risk for CHDInclusion 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 RCTRegion: NR (likely North America)Setting: Not reportedIndustry Funded: NoTreatment Duration supplement(s): 84Treatment DurationCVD Drug(s): 84Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): WarfarinDrug Category: AnticoagulantsMode of Administration: NRMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 22Supplement(s): GarlicForm of Administration: LiquidDaily Dose: 10ml | N1 = 26 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Maki200841  | N screened: 98N included/randomized: 40Age: 58%female: 64Ethnicity:- Caucasian (97)- Asian (3)Comorbidities (other than indication(s) for CVDs): NoCHD 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 periodExclusion 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 diabetesBrief Description: Subjects with mixed dyslipidemia | Study Design: Crossover RCTRegion: North AmericaSetting: Speciality clinicIndustry Funded: YesTreatment Duration supplement(s): 42Treatment DurationCVD Drug(s): 42Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): SimvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 20mgReason for taking CVD drug(s): Cardiovascular indication | N: 20Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 20 Placebo | Non-CVD Medications: NADietary Intervention(s): Therapeutic Lifestyle Changes dietExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Manuel200442  | N screened: 32N included/randomized: 24Age: 51%female: 13.7Ethnicity: NRComorbidities (other than indication(s) for CVDs): T1DMCHD Risk Level: At high risk for CHDInclusion 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: NRBrief Description: T1DM patients with high cholesterol | Study Design: Parallel RCTRegion: EuropeSetting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 183Treatment DurationCVD Drug(s): 183Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): AtorvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 20mgReason for taking CVD drug(s): Cardiovascular indication | N: 11Supplement(s): Vitamin EForm of Administration: Capsule/tabletDaily Dose: 750IU | N1 = 11 Placebo | Non-CVD Medications: NRDietary 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): NoOther Lifestyle Intervention(s): No |
| Mauro 200343  | N screened: NRN included/randomized: 8Age: 23%female: 12.5Ethnicity: NRComorbidities (other than indication(s) for CVDs: NoCHD 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, orpulmonary 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 RCTRegion: North AmericaSetting: Primary CareIndustry Funded: UnclearTreatment Duration supplement(s): 8Treatment DurationCVD Drug(s): 1 Duration of Followup: 1.5Duration of Longest Followup: 1.5 | Generic Name(s): DigoxinDrug Category: InotropicsMode of Administration: OralMean Daily Dose:0.5mg – single doseReason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 8Supplement(s): Gingko BilobaForm of Administration: Capsule/Tablet Daily Dose: 240mg | N1 = 8 No treatment | Non-CVD Medications: Subjects not on any medicationsDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| McDowell199444  | N screened: NRN included/randomized: 24Age: 43.8%female: 37.5Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: Type IIa hyperlipidaemiaExclusion Criteria: Taking regular medication for angina or hypertension oxidationBrief Description: Patients with Type IIa hyperlipidaemia | Study Design: Parallel RCT Region: EuropeSetting: Primary careIndustry Funded: UnclearTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 28Duration of Followup: 28Duration of Longest Followup: 28 | Generic Name(s): simvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 20mgReason for taking CVD drug(s): Cardiovascular indication | N: 8Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 400IU | N1 = 8 PlaceboN2 = 8No treatment | Non-CVD Medications: NRDietary Intervention(s): NRExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| McKenney 200645  | N screened: NRN included/randomized: 24Age: 30%female: 16.7Ethnicity: - Caucasian (16.7)- Hispanic (83.3)Comorbidities (other than indication(s) for CVDs: NoCHD 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 menopauseby more than 2 years, sexually abstinent, or using an acceptable method of birth control.Exclusion Criteria: Persons with a history of hypersensitivity or idiosyncratic reactionto 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 doseBrief Description: healthy adults | Study Design: Crossover RCTRegion: NR, likely North AmericaSetting: Research UnitIndustry Funded: YesTreatment Duration supplement(s): 14Treatment DurationCVD Drug(s): 14Duration of Followup: 1Duration of Longest Followup: 1 | Generic Name(s): SimvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 80mgReason for taking CVD drug(s): exploratory analysis of the effects of P-OM3 on blood coagulation and/or platelet aggregation | N: 24Supplement(s): Omega-3 (EPA, DHA or both)Form of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 24 No treatment | Non-CVD Medications: hormonal contraceptives; hormone replacement therapy allowed (portion NR)Dietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Meyer200746  | N screened: NRN included/randomized: 45Age: 56.66%female: 33Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD 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: NRBrief Description: subjects on stable statin treatment for hypercholesterolaemia (i.e. already taking statin drug for at least 3 months | Study Design: Parallel RCTRegion: Australia/New ZealandSetting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 183Treatment DurationCVD Drug(s): 183Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): 19 pts were taking simvastatin, 13 atorvastatin, 4 pravastatin, 2 cerivastatin and 2 luvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 30Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 4000mg or 8000mg | N1 = 15 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Micheletta200447  | N screened: NAN included/randomized: 16Age: 60.9%female: 35Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At high risk for CHDInclusion Criteria: patients with carotid atherosclerosis having a lumen stenosis >70% and eligible for carotid endarterectomyExclusion 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 RCTRegion: EuropeSetting: Not reportedIndustry Funded: YesTreatment Duration supplement(s): 42Treatment DurationCVD Drug(s): 42Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ASA or ticlopidinDrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 8Supplement(s): Vitamin EForm of Administration: Capsule/tabletDaily Dose: 900mg | N1 = 8 No treatment | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Miyamoto200448  | N screened: NRN included/randomized: 40Age: 60.9%female: 35Ethnicity: NRComorbidities (other than indication(s) for CVDs): NRCHD Risk Level: At high risk for CHDInclusion Criteria: patients with coronary spastic angina, in whom spontaneous angina occurred at rest.Exclusion Criteria: NRBrief Description: Patients with Coronary spastic angina | Study Design: Parallel RCTRegion: East AsiaSetting: Not reportedIndustry Funded: NoTreatment Duration supplement(s): 30Treatment DurationCVD Drug(s): 30Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR DiltiazemDrug Category: Calcium channel blockersMode of Administration: OralMean Daily Dose: 100 OR 200 mgReason for taking CVD drug(s): Cardiovascular indication | N: 20Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 400mg | N1 = 20 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Mohammed Abdul 200849  | N screened: 23N included/randomized: 16Age: 23%female: 0Ethnicity: - Caucasian (58.3)- Asian, including 3 Indians (41.7)Comorbidities (other than indication(s) for CVDs: NoCHD 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 yearsExclusion Criteria: any medical condition that could alter warfarin effects, including any clotting disorders, hepatic dysfunction or platelet dysfunctionBrief Description: healthy males | Study Design: Crossover RCTRegion: Australia/New ZealandSetting: Primary CareIndustry Funded: NoTreatment Duration supplement(s): 21Treatment DurationCVD Drug(s): 1Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): WarfarinDrug Category: Anticoagulants Mode of Administration: OralMean Daily Dose: 25mg – single doseReason for taking CVD drug(s): pharmacokineticsand pharmacodynamics | N: 4Supplement(s): GarlicForm of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 4 No treatmentN2 = 4non-relevant supplementN3 = 4Intervention3: non-relevant supplement | Non-CVD Medications: hormonal contraceptives; hormone replacement therapy allowed (portion NR)Dietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Motoyama199850  | N screened: NRN included/randomized: 60Age: 60.3%female: 49Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: At high risk for CHDInclusion Criteria: Patients with coronary spastic angina in whom spontaneous angina occurred at restExclusion Criteria: NRBrief Description: Patients with angina | Study Design: Parallel RCTRegion: East AsiaSetting: Not reportedIndustry Funded: NoTreatment Duration supplement(s): NRTreatment DurationCVD Drug(s): NRDuration of Followup: 30Duration of Longest Followup: NR | Generic Name(s): NR DiltiazemDrug Category: Calcium channel blockersMode of Administration: OralMean Daily Dose: 200mgReason for taking CVD drug(s): Cardiovascular indication | Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 300mg | Placebo (not described) | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Mueller 199151  | N screened: NRN included/randomized: 12Age: 29.67%female: 41.7Ethnicity: NRComorbidities (other than indication(s) for CVDs: NoCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: healthy adult volunteers who provided informed consentExclusion 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 countof less than 150,000/mm3 at baseline; those receiving ethanolBrief Description: healthy adults | Study Design: Parallel RCTRegion: NRSetting: NRIndustry Funded: UnclearTreatment Duration supplement(s): 21Treatment DurationCVD Drug(s): 1Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ASADrug Category: Antiplatelets Mode of Administration: OralMean Daily Dose: 325mg - single doseReason for taking CVD drug(s): bleeding-time changes associated with aspirin in normal volunteers who ingest omega-3s | N: 6Supplement(s): Omega-3 (EPA, DHA or both)Form of Administration: Capsule/tabletDaily Dose: 8000mg | N1 = 6Placebo | Non-CVD Medications: NRDietary Intervention(s): subjects asked not to change dietExercise Intervention(s): subjects asked not to change exerciseOther Lifestyle Intervention(s): subjects asked not to change lifestyle |
| Napoli199852  | N screened: NRN included/randomized: 220Age: 37.2%female: 36Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD 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 feedingBrief Description: hypercholesterolemic patients with normal concentrations of triglycerides | Study Design: Parallel RCTRegion: EuropeSetting: Primary careIndustry Funded: YesTreatment Duration supplement(s): 84Treatment DurationCVD Drug(s): 84Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): PravastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 20-40mgReason for taking CVD drug(s): Cardiovascular indication | N: 60Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 100mg | N1 = 52 no treatmentN2 = 52Placebo | Non-CVD Medications: NRDietary Intervention(s): American Heart Association Step I dietExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Neil (2010)53 | N screened: NRN included/randomized:Age: 64 (SD 11.5) %female: 41.6Ethnicity: NRComorbidities (other than indication(s) for CVDsCHD Risk Level: at high risk of CHDInclusion 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 therapyExclusion 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 RCTRegion: NRSetting: primary careIndustry Funded: Yes (funded by Pfizer)Treatment Duration supplement(s): 120 daysTreatment DurationCVD Drug(s): similar to dietary treatmentDuration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): Lipitor/ atorvastatinDrug Category: Antilipidemic (HMG Co-A Reductase Inhibitor)Mode of Administration: OralMean Daily Dose: 20 mg/dReason for taking CVD drug(s): cardiovascular indication | N: 163Supplement(s): omega-3 fatty acids Form of Administration: Capsule/TabletDaily Dose: 2 g/day | N1 = 169 no treatmentN2 = None | Non-CVD Medications: NRDietary Intervention(s): None Exercise Intervention(s): NoneOther 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: NRN included/randomized: 41Age: 46.75%female: 29.2Ethnicity: NRComorbidities (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 hyperlipemiaExclusion Criteria: NRBrief Description: patients with combined hyperlipemia | Study Design: Parallel RCTRegion: EuropeSetting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 35Treatment DurationCVD Drug(s): 35Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): Drug Category:Mode of Administration: OralMean Daily Dose:Reason for taking CVD drug(s): Cardiovascular indication | N: 21Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 4000mg | N1 = 20 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Nordøy 200355  | N screened: NRN included/randomized: 42Age: 49.8%female: 28.5Ethnicity: NRComorbidities (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 hyperlipemiaExclusion Criteria: NRBrief Description: patients with hyperlipemia | Design: Parallel RCTRegion: EuropeSetting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 35Treatment DurationCVD Drug(s): 35Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): atorvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: 10mgReason for taking CVD drug(s): Cardiovascular indication | N: 22Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 2g | N1 = 20Placebo | Non-CVD Medications: NRDietary 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): NoOther Lifestyle Intervention(s): No |
| Paolisso199556  | N screened: NRN included/randomized: 30Age: 73.8%female: 40Ethnicity: NRComorbidities (other than indication(s) for CVDs): obeseCHD Risk Level: At high risk for CHDInclusion Criteria: NRExclusion Criteria: NRBrief Description: elderly patients with CHD | Study Design: Crossover RCTRegion: NRSetting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 120Treatment DurationCVD Drug(s): 120Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR nifedipineDrug Category: Calcium channel blockersMode of Administration: OralMean Daily Dose: 88mgReason for taking CVD drug(s): Cardiovascular indication | N: NRSupplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 900mg | N1 = NRPlacebo | Non-CVD Medications: NADietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Paolisso199257  | N screened: NRN included/randomized: 18Age: 64%female: 50Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD 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 RCTRegion: NR (likely Europe)Setting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 56Treatment DurationCVD Drug(s): 56Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): hydrochlorthiazideDrug Category: Diuretic: Thiazide/Thiazide-likeMode of Administration: OralMean Daily Dose: 25mgReason for taking CVD drug(s): Cardiovascular indication | N: 9Supplement(s): MagnesiumForm of Administration: Capsule/TabletDaily Dose: 4500mg | N1 = 9Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Playford200358  | N screened: NRN included/randomized: 40Age: 53.1%female: 30Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At high risk for CHDInclusion 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 >4Exclusion 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 RCTRegion: Australia/New ZealandSetting: Not reportedIndustry Funded: NoTreatment Duration supplement(s): 84Treatment DurationCVD Drug(s): 84Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): NR FenofibrateDrug Category: Antilipidemic: FibrateMode of Administration: OralMean Daily Dose: 200mgReason for taking CVD drug(s): Cardiovascular indication | N: 20Supplement(s): Coenzyme Q10Form of Administration: NRDaily Dose: 200mg | N1 = 20 Placebo | Non-CVD Medications: NRDietary Intervention(s): patients were on an isocalroic fat-modified diet for the 6 week run-in periodExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Reyes 198459 | N screened: NRN included/randomized: 21Age: 56.7%female: 80.9Ethnicity:- Caucasian (100)Comorbidities (other than indication(s) for CVDs): NoCHD 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 therapyExclusion 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 RCTRegion: NR (likely Africa)Setting: NRIndustry Funded: UnclearTreatment Duration supplement(s): 21Treatment DurationCVD Drug(s): 21Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): hydrochlorothiazideDrug Category: Diuretic: Thiazide/Thiazide-likeMode of Administration: OralMean Daily Dose:50mgReason for taking CVD drug(s): Cardiovascular indication | N: 13Supplement(s): MagnesiumForm of Administration: Capsule/TabletDaily Dose: 15.78 mmol MgCl2 | N1 = 8 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Roth 200960 | N screened: 596N included/randomized: 167Age: 52.04%female: 73.6Ethnicity:- Caucasian (88.6)- African-American (1.8)- Hispanic (7.2)- Other, not specified (6.6)Comorbidities (other than indication(s) for CVDs): DM, high BMICHD 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/m2Exclusion 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 excludedBrief Description: subjects with very high TG levels (> or =500 mg/dL) | Study Design: Parallel RCTRegion: North AmericaSetting: NRIndustry Funded: YesTreatment Duration supplement(s): 56Treatment DurationCVD Drug(s): 56Duration of Followup: 56Duration of Longest Followup: 56 | Generic Name(s): fenofibratesDrug Category: Antilipidemic: FibrateMode of Administration: OralMean Daily Dose:130mgReason for taking CVD drug(s): Cardiovascular indication | N: 81Supplement(s): Omega-3Form of Administration: NRDaily Dose: 4000mg | N1 = 82No treatment | Non-CVD Medications: NRDietary Intervention(s): a diet run in period; reinforced NCEP TLC diet during the tx periodExercise Intervention(s): maintaining currect physical activityOther Lifestyle Intervention(s): No |
| Sconce200761  | N screened: NRN included/randomized: 70Age: NR%female: 50Ethnicity: Caucasian(100)Comorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: At high risk for CHDInclusion 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 controlExclusion 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 consumptionBrief Description: Patients with atrial fibrillation anticoagulated with warfarin for thromboembolic prophylaxis | Study Design: Parallel RCTRegion: EuropeSetting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 180Treatment DurationCVD Drug(s): 180Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): warfarinDrug Category: anticoagulantsMode of Administration: OralMean Daily Dose: NR (various starting and ending dosages)Reason for taking CVD drug(s): Cardiovascular indication | N: 35Supplement(s): Vitamin KForm of Administration: Capsule/TabletDaily Dose: 0.15mg | N1 = 33 Placebo: | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Steiner199562  | N screened: NRN included/randomized: 100Age: 71%female: 58Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: At high risk for CHDInclusion 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 diseaseExclusion Criteria: NRBrief Description: patients with transient ischemic attacks, minor strokes, or residual ischemic neurologic deficits | Study Design: Parallel RCTRegion: NR (likely North America)Setting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 730Treatment DurationCVD Drug(s): 730Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 325mgReason for taking CVD drug(s): Cardiovascular indication | N: 52Supplement(s): Vitamin EForm of Administration: Capsule/TabletDaily Dose: 400IU | N1 = 48Placebo (not described) | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Sutken200663 | N screened: NRN included/randomized: 22Age: 29.5%female: 50Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: Hyperlipidemic subjectsExclusion 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 EastSetting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 30Treatment DurationCVD Drug(s): 30Duration of Followup: 30Duration of Longest Followup: NR | Generic Name(s): GemfibrozilDrug Category: Antilipidemic: FibrateMode of Administration: OralMean Daily Dose: 1200 mgReason for taking CVD drug(s): Cardiovascular indication | N: 12Supplement(s): Vitamin EForm of Administration: NRDaily Dose: 600 mg | N1 = 10 No treatmentN2 = 12Vitamin E  | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Sutken 200663  | N screened: NRN included/randomized: 45Age: 71.5%female: 46.7Ethnicity: NR Comorbidities (other than indication(s) for CVDs: NoCHD Risk Level: At low risk for CHD 90-1 risk factors)Inclusion Criteria: Hyperlipidemic subjectsExclusion 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 TrialRegion: Middle EastSetting: Specialty ClinicIndustry Funded: UnclearTreatment Duration supplement(s): 30Treatment DurationCVD Drug(s): 30Duration of Followup: 30Duration of Longest Followup: NR | Generic Name(s): GemfibrozilDrug Category: Antilipidemic: FibrateMode of Administration: OralMean Daily Dose: 1200 mgReason for taking CVD drug(s): Cardiovascular indication | N: 20Supplement(s): Vitamin EForm of Administration: NRDaily Dose: 600 mg | N1 = 23 No treatmentN2 = 22Vitamin E  | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Svaneborg 200264  | N screened: NRN included/randomized: 14Age: 31%female: 0Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: healthy, nonsmoking, nonobese menExclusion Criteria: NRBrief Description: healthy, nonsmoking, nonobese men | Study Design: Parallel RCTRegion: NR (likely Europe)Setting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 14Treatment DurationCVD Drug(s): NADuration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: ParenteralMean Daily Dose: 100mgReason for taking CVD drug(s): Aim was to test platelet function with ASA & n-3s | N: 12Supplement(s): Fish oils/marineForm of Administration: Capsule/TabletDaily Dose: 10000mg | N1 = 6 Placebo | Non-CVD Medications: NADietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Tankanow200365  | N screened: 11N included/randomized: 11Age: 28%female: 50Ethnicity: NRComorbidities (other than indication(s) for CVDs: NoCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: age > 18 years, serumcreatinine < 1.2 mg/dL, and bilirubin < 1.5 mg/dLExclusion Criteria: Individuals taking concurrent scheduled medications (excluding oral contraceptives), those with significantmedical histories, and smokers and pregnant femalesBrief Description: Healthy subjects | Study Design: Crossover RCTRegion: North AmericaSetting: Primary CareIndustry Funded: UnclearTreatment Duration supplement(s): 21Treatment DurationCVD Drug(s): 10Duration of Followup: 0.5Duration of Longest Followup: 3 | Generic Name(s): DigoxinDrug Category: InotropicsMode of Administration: OralMean Daily Dose: 0.25mgReason for taking CVD drug(s):Pharmacokinetics and pharmackodynamic study | N: 8Supplement(s): HawthornForm of Administration: Capsule/Tablet Daily Dose: 900mg | N1 = 8 No treatment | Non-CVD Medications: oral contraceptives not excludedDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Watson199966 | N screened: NRN included/randomized: 30Age: 55%female: 13Ethnicity: NRComorbidities (other than indication(s) for CVDs): Not reportedCHD Risk Level: At high risk for CHDInclusion Criteria: between 18 and 75 years of age with ischemic or idiopathic dilated cardiomyopathyExclusion 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 pregnantBrief Description: between 18 and 75 years of age with ischemic or idiopathic dilated cardiomyopathy | Study Design: Crossover RCTRegion: Australia/New ZealandSetting Industry Funded: UnclearTreatment Duration supplement(s): 84Treatment DurationCVD Drug(s): 84Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ACE inhibitors (no description)Drug Category: RAAS Antagonist: ACEIMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indicationGeneric Name: FurosemideDrug Category: Diuretic: LoopMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indicationGeneric Name:digoxin, also hydralazine and/or nitratesDrug Category: InotropicsMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: NRSupplement(s): Coenzyme Q10Form of Administration: Capsule/TabletDaily Dose: 99mg | N1 = NR Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Wirell199467 | N screened: NR N included/randomized: 40Age: 35.4%female: 23Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: mild to moderate essential hypertensionExclusion 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 mmHgBrief Description: Patients with mild to moderate essential hypertension | Study Design: Crossover RCTRegion: EuropeSetting: Speciality clinicIndustry Funded: UnclearTreatment Duration supplement(s): 56Treatment DurationCVD Drug(s): 56Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): metoprololDrug Category: b-blockersMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indicationGeneric Name(s): atenololDrug Category: b-blockersMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indicationGeneric Name(s): pindolol & propanololDrug Category: b-blockersMode of Administration: OralMean Daily Dose: NRReason for taking CVD drug(s): Cardiovascular indication | N: 19Supplement(s): MagnesiumForm of Administration: Powder mixed with water Daily Dose: 365mg | N1 = 20 Placebo | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Wolf200668  | N screened: NRN included/randomized: 50Age: 27.2%female: 0Ethnicity:- Caucasian (98)- Asian (2)Comorbidities (other than indication(s) for CVDs): NoCHD 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 weeksExclusion Criteria: Intake of medication containing ASA, anticoagulants,NSAIDs, sulfinpyrazone, ticlopidine and lipid-lowering agentsBrief Description: healthy subjects | Study Design: Crossover RCTRegion: EuropeSetting: General communityIndustry Funded: YesTreatment Duration supplement(s): 7Treatment DurationCVD Drug(s): 7Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): ASADrug Category: AntiplateletsMode of Administration: OralMean Daily Dose: 500mgReason 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: 50Supplement(s): Gingko bilobaForm of Administration: Capsule/TabletDaily Dose: 240mg | N1 = 50 No treatment | Non-CVD Medications: paracetamol (15) and Sinupret (4)Dietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Yamamoto199569  | N screened: NRN included/randomized: NRAge: 59.6%female: 22.7Ethnicity: NRComorbidities (other than indication(s) for CVDs): NoCHD Risk Level: At high risk for CHDInclusion Criteria: variant angina, angiographically normal- appearing coronary artery after ISDM administrationExclusion Criteria: history of MI, DM, hypertension, heart failure or hyperlipidemiaBrief Description: Participants with variant angina | Study Design: Parallel RCTRegion: East Asia Setting: Primary careIndustry Funded: YesTreatment Duration supplement(s): 112Treatment DurationCVD Drug(s): 112Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): diltiazemDrug Category: Calcium channel blockersMode of Administration: OralMean Daily Dose: 90-120mgReason for taking CVD drug(s): Cardiovascular indication | N: 12Supplement(s): Omega-3Form of Administration: Capsule/TabletDaily Dose: 1800mg | N1 = 10No treatment | Non-CVD Medications: NRDietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Young200770  | N screened: NRN included/randomized: 44Age: 59%female: 50Ethnicity: NRComorbidities (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 therapyExclusion 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 RCTRegion:NR (likely Australia)Setting: Not reportedIndustry Funded: UnclearTreatment Duration supplement(s): 63Treatment DurationCVD Drug(s): 63Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): simvastatinDrug Category: Antilipidemic: HMG Co-A Reductase InhibitorMode of Administration: OralMean Daily Dose: Staring 10mg, ending 40mgReason for taking CVD drug(s): NR | N = 22Supplement(s): Coenzyme Q10Form of Administration: Capsule/TabletDaily Dose: 200mg | N1 = 22 Placebo | Non-CVD Medications: Ezetimibe (4)Dietary Intervention(s): NoExercise Intervention(s): NoOther Lifestyle Intervention(s): No |
| Yuan 200471  | N screened: NRN included/randomized: 21Age: 27.84%female: 55Ethnicity: - Caucasian (10)- African-American (5)- Hispanic (3)- Asian (2)Comorbidities (other than indication(s) for CVDs: NRCHD Risk Level: At low risk for CHD (0-1 risk factors)Inclusion Criteria: NRExclusion Criteria: NRBrief Description: Healthy patients | Study Design: Parallel RCTRegion: North America Setting: Primary CareIndustry Funded: NoTreatment Duration supplement(s): 28Treatment DurationCVD Drug(s): 6Duration of Followup: End of treatment periodDuration of Longest Followup: End of treatment period | Generic Name(s): WarfarinDrug Category: AnticoagulantsMode of Administration: OralMean Daily Dose: 5mgReason for taking CVD drug(s): Pharmacokinetics and pharmackodynamic study | N: 12Supplement(s): GinsengForm of Administration: Capsule/Tablet Daily Dose: 2000mg  | N1 = 8 Placebo | Non-CVD Medications: NADietary 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 habitsExercise Intervention(s): NoOther Lifestyle Intervention(s): No |