Appendix Evidence Table C84. Overview of ACEI versus conventional therapy without ACEI trial

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Study/Region/****Funding Source** | **Inclusion/Exclusion Criteria** | **Patient Characteristics (expressed in means unless otherwise noted)** | **Intervention/Duration** | **Study Quality** |
| Cinotti, 200162CountryItaly, multisiteFunding Source: Industry | Inclusion: ages 18-70 years; chronic renal insufficiency due to primary renoparenchymal diseases; no ACEI therapy for at least 3 months; renal insufficiency of at least 12 months with creatinine clearance between 20 and 50 ml/min/1.73m2 with variation <30% in at least 3 determinations during past 3 months; hypertension (either nontreated DBP ≥95 mmHg or well-documented treatment with antihypertensive drugs\*); proteinuria ≤1.0 g/dayExclusion: nephropathy secondary to diabetes or other systemic diseases; malignant hypertension or previous antihypertensive treatment with >2 drugs; cerebrovascular events in the last 6 months or MI in the last 3 months; heart failure, angina, or other major cardiac diseases; significant liver, hemopoietic, or endocrine pathology; concomitant therapy with steroids or immuosuppressive drugs and erythropoietin; pregnancy; lactation; serum potassium <3 mEq/l or >5.8 mEq/l; hypersensitivity or any contraindication to use of ACEI\*During 3 month run-in period, patients to follow 0.8 g/kg IBW protein and 3-4 g/day salt diet. Antihypertensive agents (CCB, BB or alpha blocker) continued or added. Patients required to be “compliant” and have stable DBP ≤90 mm Hg with one or two drugs at end of run-in to proceed to randomization. | N=131Age (yr): 50.8Gender (Male %): 66Race/Ethnicity (%): NRWeight (kg): 71.4BMI: NRSystolic BP (mm Hg): 141.6Diastolic BP (mm Hg): 85.7CKD stage: NRSerum creatinine (mg/dL): 2.3Creatinine clearance (mL/min): 36.3Albuminuria (μg/min): NR Proteinuria (mg/day): 512Albumin/creatinine ratio (mg/g): NRmeasured GFR (ml/min/1.73m2): 35.8HbA1c (%): NRTotal cholesterol (mg/dL): NRLDL cholesterol (mg/dL): NRDiabetes (%): 0History of HTN (%): 100Dyslipidemia (%): NRHistory of CAD (%): NRHistory of CHF (%): 0Peripheral arterial disease (%): NRHistory of MI (%): NR (no recent)History of Stroke (%): NR (no recent)Current smoker (%): NRHistory of AKI (%): NR | n=66 Lisinopril 5-10 mg/day or Lisinopril 10 mg/day with other antihypertensive drug (L)n=65 Conventional antihypertensive therapy (without ACEI) (C)NSAID use limited to 7 days, ASA allowed at <500 mg/d.Followup period: 22.5 monthsStudy withdrawals (%): No information reported on study withdrawals | Allocation Concealment: UnclearBlinding: Open-labelIntention to Treat Analysis (ITT): YesWithdrawals/Dropouts adequately described: No data reported on withdrawals/dropouts. |

ACEI = angiotensin converting enzyme inhibitor; ACR = albumin/creatinine ratio; AER = albumin excretion rate; AKI = acute kidney injury; ARB = angiotensin II receptor blocker; BB = bete blocker; BMI = body mass index; BP = blood pressure; CAD = coronary artery disease; CCB = calcium channel blocker; CHD = coronary heart disease; CHF = congestive heart failure; CKD = chronic kidney disease; CV = cardiovascular; CVA = cerebrovascular accident; DBP = diastolic blood pressure; DM = diabetes mellitus; GFR = glomerular filtration rate; HbA1c = hemoglobin A1c; HTN = hypertension; LDL = low density lipoprotein; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NR = not reported; NSAIDS = [non-steroidal anti-inflammatory drug;](http://en.wikipedia.org/wiki/Non-steroidal_anti-inflammatory_drug) PVD = peripheral vascular disease; RCT = randomized controlled trial; SBP = systolic blood pressure; UACR = urinary albumin/creatinine ratio; UAE = urinary albumin excretion