

Summary: A randomized double-blind, placebo-controlled-parallel-group study to determine whether, in patients with type 2 diabetes at high risk for cardiovascular and renal events, aliskiren, on top of conventional treatment, reduces cardiovascular and renal morbidity and mortality.

Inclusion Criteria:

- Male or female patients > 35 years of age.
- Pt with a diagnosis of type 2 diabetes.
- Pt with macroalbuminuria or cardiovascular disease with one of the following events; Previous (MI), Previous stroke, Heart failure or Coronary Artery Disease.
- Pt must be either on one ACE or ARB for 3 months with no adjustments.

Exclusion Criteria:

- History of cardiovascular event (stroke, TIA, MI, unstable angina, CABG, PCI, hospitalization due to HF) during 3 months prior to visit 1.
- Concomitant treatment with 2 or more rennin-angiotensin-aldosterone system blocking agents apart from the study medications, e.g. ACEI, ARB or aldosterone antagonist or any rennin inhibitor.
- Second or third degree heart block without pacemaker.
- Hypertension (at visit 3): any patients with a msSBP>135 and <170 mmHg or ms DBP >85 and <110 mmHg unless treated with at least 3 anti-hypertensive medications.
- Concurrent potentially life threatening arrhythmia or other uncontrolled arrhythmia.
- Clinical significant valvular heart disease.
- Type 1 Diabetes defined as onset of disease before the age 35 and need of permanent insulin treatment within one year of diagnosis.
- History of active cancer or a history of cancer with less than 5 years disease free survival time.
- History of major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy or bowel resection.
- Pregnant or nursing (lactating) women.

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