

AQUARIUS

Principal Investigator:

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Sponsor:

Novartis

Study Purpose:

A 104 week, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the efficacy of aliskiren on the progression of atherosclerosis in patients with coronary artery disease when added to optimal background therapy

Objective:

To evaluate the effect of aliskiren 300 mg, in addition to optimized background therapy, compared to placebo on progression of coronary atherosclerosis (defined as change from baseline in percent atheroma volume) as assessed by IVUS in patients with CAD and blood pressure in the prehypertensive (high normal) range with or without treatment for hypertension.

Inclusion Criteria:

- ♥ Patients with CAD who have blood pressure in the pre-hypertensive range defined as a msSBP ≥ 125 and ≤ 139 mmHg and a msDBP < 90 mmHg.
- ♥ Patients with or without current treatment for hypertension
- ♥ Angiographic evidence of coronary artery disease
- ♥ At least 2 qualifying Cardiovascular risk factors at Visit 1

Exclusion Criteria:

- ♥ Baseline IVUS determined unacceptable
- ♥ Patients requiring treatment with disallowed study medications
- ♥ Patients with clinically significant heart disease
- ♥ Previous or current diagnosis of heart failure (NYHA Class IV) or a documented left ventricular ejection fraction of $< 25\%$
- ♥ Patients requiring treatment with any 2 of the following classes of medication at Visit 1 or Visit 2:
 - Angiotensin converting enzyme inhibitors
 - Angiotensin receptor blockers
 - aldosterone receptor blockers or a direct renin inhibitor.
- ♥ Other conditions may apply

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Status:

Active enrollment

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.