dal-GenE

NCT02525939

Principal Investigator: Dr. John Collins (St. Mary's of Michigan)

Condition: Acute Coronary Syndrome

Drug: Dalcetrapib vs. Placebo

Official Title: A Phase III, Double-blind, Randomized Placebo-controlled Study to Evaluate the Effects of Dalcetrapib on Cardiovascular (CV) Risk in a Genetically Defined Population With a Recent Acute Coronary Syndrome (ACS): The Dal-GenE Trial.

Sponsor: DalCor Pharmaceuticals

Purpose: A placebo-controlled, randomized, double-blind, parallel group, phase III multicenter study in subjects recently hospitalized for ACS and with the appropriate genetic profile. Subjects will provide informed consent before any study-specific procedures are performed. Subject enrollment may begin in the hospital and will continue following release from the hospital. Screening procedures may be performed at the time of the index ACS event or anytime thereafter, with the condition that randomization must occur within the mandated window (4-12 weeks after the index event). Subjects will be assessed based on their medical history. Those who are likely to qualify will undergo Genotype Assay testing to evaluate genetic determination for the presence of AA genotype.

Inclusion Criteria:

- Subjects with the appropriate genetic background and recently hospitalized for ACS (between 4 and 12 weeks following the index event), will be enrolled in this trial.
- AA genotype at variant gene as determined by Genotype Assay testing, conducted at a designated investigational testing site (ITS).
- Clinically stable, ie, free of ischemic symptoms at rest or with minimal exertion for at least 1 week prior to randomization.
- Prior to randomization, subject must have evidence of guidelines-based management of LDL-C, at a minimum to include medical and dietary treatment to a target level of LDL-C < 100 mg/dl (< 2.6 mmol/L).

Exclusion Criteria:

- Females who are pregnant (negative pregnancy test required for all women of child-bearing potential at Visit 2, Day 0) or breast-feeding.
- Women of childbearing potential (women who are not surgically sterile or postmenopausal defined as amenorrhea for > 12 months) who are not simultaneously using two effective contraceptive methods, and one of which being a barrier method (diaphragm, cervical cap, male condom, etc.).
- New York Heart Association (NYHA) Class III or IV heart failure.
- Last known hemoglobin < 10 g/dL.
- Index ACS event presumed due to uncontrolled hypertension.

Source: https://clinicaltrials.gov/ct2/show/NCT02525939
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