HPS-4/TIMI 65/ORION-4: A Double-blind Randomized Placebo-controlled Trial Assessing the Effects of Inclisiran on Clinical Outcomes Among People With Atherosclerotic Cardiovascular Disease

Status: Recruiting

Eligibility Criteria

Age: 18 Years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

History or evidence of at least one of the following: Prior MI; or Prior ischemic stroke; or Peripheral artery disease as evident by prior lower extremity artery revascularization or aortic aneurysm repair.

Exclusion Criteria:

None of the following must be satisfied (based on self-reported medical history): Acute coronary syndrome or stroke less than 4 weeks before the Screening visit or during the Run-in period; Coronary revascularization procedure planned within the next 6 months; Known chronic liver disease; Current or planned renal dialysis or transplantation; Previous exposure to inclisiran or participation in a randomized trial of inclisiran; Previous (within about 3 months), current or planned treatment with a monoclonal antibody targeting PCSK9, or with a drug known to be contra-indicated with inclisiran (none currently known); Known to be poorly compliant with clinic visits or prescribed medication; Medical history that might limit the individual's ability to take trial treatments for the duration of the study (e.g. severe respiratory disease; cancer or evidence of spread within approximately the last 5 years, other than non-melanoma skin cancer; or history of alcohol or substance misuse) or may put the individual at significant risk in the opinion of the investigator (or their authorised deputy) if he/she were to participate in the trial; Women of child-bearing potential, current pregnancy, or lactation; Current participation in a clinical trial with an unlicensed drug or device; or Staff personnel directly involved with the study and any family member of the investigational study staff.

Conditions & Interventions

Conditions:
Atherosclerotic Cardiovascular Disease, Heart & Vascular
Keywords:
Cardiovascular, Cholesterol, Heart Disease, Inclisiran, LDL Cholesterol, Lipid, PCSK9, RNA interference

More Information

Description: The HPS-4/TIMI 65/ORION-4 study aims to provide evidence about both the efficacy and safety of inclisiran. It is intended to be conducted at approximately 150 clinical sites in Europe (primarily in the UK) and North America. Approximately 15,000 participants aged 55 years or older with pre-existing atherosclerotic cardiovascular disease will be randomized between inclisiran sodium 300 mg and matching placebo (given by subcutaneous injection on the day of randomization, at 3 months and then every 6-months) in a 1:1 ratio for a planned median duration of about 5 years. Consistent with relevant guideline recommendations for people with vascular disease, it is intended that participants be on intensive background LDL-lowering therapy (for example, atorvastatin 40 or 80 mg daily, simvastatin 40 or 80 mg daily, or rosuvastatin 20 or 40 mg daily) at screening. In order to achieve a target LDL cholesterol reduction of at least 1.2 mmol/l [45 mg/dL], it is intended to recruit a study population with a mean LDL cholesterol of at least 2.6 mmol/l [100mg/dL] at baseline.
Contact(s): Kaylee Slepica - kaylee.slepica@fairview.org
Principal Investigator: Les Forgosh
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System ID: NCT03705234