A Study to Investigate LDL-cholesterol Lowering With Inclisiran Compared to Bempedoic Acid in Patients With Atherosclerotic Cardiovascular Disease.

Last Update: Mar 14, 2025
A Randomized, Multicenter, Open-label Trial Comparing the Effectiveness of Inclisiran to Bempedoic Acid on LDL Cholesterol (LDL-C) Lowering in Participants With Atherosclerotic Cardiovascular Disease (VICTORION-CHALLENGE)
ClinicalTrials.gov Identifier:
NCT06431763
Novartis Reference Number:CKJX839A1DE02
See if you Pre-qualify
All compounds are either investigational or being studied for (a) new use(s). Efficacy and safety have not been established. There is no guarantee that they will become commercially available for the use(s) under investigation.

Study Description

This study is a phase IV, open-label, randomized study designed to evaluate the efficacy of Inclisiran vs. bempedoic acid (BPA) in 400 adult subjects (≥ 18 years) at very high and high risk for cardiovascular events as defined by the cardiovascular risk categories in the 2019 ESC/EAS guidelines for the management of dyslipidemias (Mach et al 2020) and elevated levels of LDL-C (≥ 70 mg/dL) despite being on a maximally tolerated high-intensity (HI) statin dose (+/- Ezetimibe). Currently, BPA is recommended ahead of injectables by German HTA body (GBA). A head-to-head trial is proposed to provide robust scientific data on the superiority of Inclisiran vs. BPA and to support the early use of Inclisiran. During the screening period study eligibility will be assessed and the participants' individual LDL-C target according to guideline (Mach et al., 2020) will be determined. Among other criteria, at screening, a participant must be on a stable maximally tolerated dose of a HI statin with either atorvastatin ≥40 mg once a day (QD) or rosuvastatin ≥20 mg QD (+/- Ezetimibe \[10mg\]) for ≥ 4 weeks with which, however, a target LDL-C of \< 70 mg/dL is not reached.

During the open-label treatment period, all participants, who fulfill the inclusion/exclusion criteria, will be randomized at V1 (Day 1) in a 1:1 open-label fashion to either Inclisiran sodium 300 mg s.c. (administered at Day 1 and Day 90) or to BPA tablets 180 mg p.o. (given once daily). Participants will be required to maintain their background lipid-lowering treatment (maximally tolerated statin dose +/- Ezetimibe) unchanged for the duration of the study. The end of treatment (EOT) is reached at day 150.

A Safety-Follow-up call will be conducted 30 days after EOT visit (Day 180).

The overall study duration is approximately 190 days but can vary depending on individual screening and the visit windows allowed for the treatment period and EOS visit.

Condition

Hypercholesterolemia
Phase
Phase4
Overall Status
Recruiting
Number of Participants
400
Start Date
Jun 21, 2024
Completion Date
Sep 30, 2025
Gender
All
Age(s)
18 Years - 99 Years (Adult, Older Adult)

Interventions

Drug

BPA

180 mg daily per oral
Drug

Inclisiran sodium

300 mg s.c. administered at day 1 and day 90

Eligibility Criteria

Inclusion Criteria:

1. Fasting LDL-C ≥ 70 mg/dL at screening
2. Participants must be on a stable (≥ 4 weeks) and well-tolerated lipid-lowering regimen (with or without Ezetimibe \[10mg\]) that must include a high-intensity statin therapy with either atorvastatin ≥40 mg QD or rosuvastatin ≥20 mg QD in a maximally tolerated or maximally approved dose at screening
3. Participants categorized as very high or high CV risk, as defined below:

* Very high risk participants with at least one of the following:

* Documented ASCVD: ACS: Unstable angina or myocardial infarction, Stable angina, Coronary revascularization, Unequivocally documented ASCVD upon prior imaging, Stroke and Transient Ischaemic Attack (TIA), Peripheral artery disease (PAD)
* Diabetes mellitus (DM) with target organ damage (defined as microalbuminuria, retinopathy, or neuropathy), or at least ≥ 3 major risk factors, or early onset of Type 1 DM of long duration (\< 20 years)
* A calculated SCORE2 ≥ 7.5 % for age \< 50 years; SCORE2 ≥ 10 % for age 50-69 years; SCORE2-OP ≥ 15 % for age ≥ 70 years to estimate 10-year risk of fatal and non-fatal CVD
* Pre-existing diagnosis of heterozygous familial hyper-cholesterolemia (HeFH) with ASCVD or with another

major risk factor OR
* High risk participants with at least one of the following:

* Markedly elevated single risk factors, in particular total cholesterol \> 310 mg/dL, LDL-C \> 190 mg/dL, or blood pressure ≥ 180/110 mmHg
* Pre-existing diagnosis of HeFH without other major risk factors
* DM without target organ damage (defined as microalbuminuria, retinopathy, or neuropathy), with DM duration ≥ 10 years or other additional risk factor
* Moderate chronic kidney disease (eGFR 30-59 mL/min/1.73m2)
* A calculated SCORE2 2.5 to \< 7.5 % for age \< 50 years; SCORE2 5 to \< 10 % for age 50-69 years; SCORE2-OP 7.5 to \< 15 % for age ≥ 70 years to estimate 10-year risk of fatal and non-fatal CVD as defined by the cardiovascular risk categories in the 2019 ESC/EAS guideline (Mach et al 2020), and updated SCORE2 and SCORE2-OP (Hageman et al 2021, de Vries et al 2021, Visseren et al 2021). Further details for documented ASCVD will be provided in the protocol.
4. Fasting triglyceride \< 400 mg/dL at screening

Exclusion Criteria:

1. Acute coronary syndrome, ischemic stroke, peripheral arterial revascularization procedure or amputation due to atherosclerotic disease \< 4 months prior to screening visit or V1.
2. Planned or expected cardiac, cerebrovascular or peripheral artery surgery or coronary re-vascularization within 6 months after screening visit.
3. Heart failure NYHA class IV at screening or V1.
4. Participants on more than one other lipid-lowering drug on top of statin at screening visit.
5. Previous treatment with a mAb directed towards PCSK9 (e.g., evolocumab, alirocumab) or planned use after screening visit.
6. Previous treatment prior to screening with BPA within 90 days
7. Previous exposure to Inclisiran or any other non-mAb PCSK9-targeted therapy, either as an investigational or marketed drug.

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