LATAM LOWERS LDL-C

Last Update: Mar 14, 2025
Latin America Lipid Optimization After Acute Event in Patients With AthErosclerotic CardiovasculaR DiseaSe and High LDL-C
ClinicalTrials.gov Identifier:
NCT06501443
Novartis Reference Number:CKJX839A1MX02
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 is an open label, patient-level 1:1 randomized clinical trial in a multi-country study aiming to evaluate the real-world impact of inclisiran + Usual Care (UC) vs UC alone on LDL-C lowering, patient-reported outcomes, and healthcare resource utilization in an in-hospital population of patients, admitted during the acute setting, stabilized and before discharge, following an acute cardiovascular event. The primary objective is to evaluate the impact of inclisiran plus usual care on LDL-C lowering versus usual care after acute MI, confirmed ischemic stroke, or urgent coronary revascularization.

The secondary objective is to compare the LDL-C reduction of both arms in target population.

Study completion for an individual participant is defined as when the participant finishes the last visit (day 330) and any assessments associated with that visit.

Condition
Hypercholesterolaemia
Phase
Phase4
Overall Status
Recruiting
Number of Participants
520
Start Date
Feb 11, 2025
Completion Date
Nov 29, 2026
Gender
All
Age(s)
18 Years - 100 Years (Adult, Older Adult)

Interventions

Drug

KJX839

Inclisiran in solution for subcutaneous injection on day 1, day 90, and day 270
Drug

Usual care

Treatment after acute event approved in the country where patient is based. It may include educational intervention according to each country guidelines

Eligibility Criteria

Inclusion Criteria:

* Admitted for MI (Type 1 NSTEMI or STEMI), urgent (i.e., non-elective) coronary revascularization (PCI or CABG) or confirmed ischemic stroke.
* Stable patient: Patient will be considered stable if they did not suffer cardiac arrest at presentation or if in the last 24 hours before randomization:

* Was not in cardiogenic shock.
* Did not required invasive hemodynamic, inotropic or vasopressor support.
* Participants are required to be eligible for receiving inclisiran in accordance to approved local label.

* Of note, patients who are initiated on statin therapy during the same hospitalization will not be excluded, as we expect a proportion of patients at baseline to not yet be on statin therapy in this real-world study. This will enhance the generalizability and pragmatic aspects of the study. However, because initiation of statin therapy at or near the time of enrollment could impact the primary outcome (if there is imbalance between the arms, or if there is differential stopping of statin therapy between the arms), we will stratify randomization by this factor and will pre-specify analyses in those who have vs. have not been initiated on statin therapy during the same hospitalization.

Exclusion Criteria:

* Currently on PCSK9i therapy (within last 3 months)
* Current participation in another clinical study with another study drug
* Active liver disease defined as any known current infectious, neoplastic, or metabolic pathology of the liver at the Baseline Visit
* Pregnant or nursing (lactating) women
* Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using highly effective methods of contraception

Argentina

Novartis Investigative Site

Recruiting

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Brazil

Novartis Investigative Site

Recruiting

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Recruiting

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Worldwide Contacts

If the location of your choosing does not feature any contact detail, please reach out using the information below.

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Source URL: *https://prod1.novartis.com/clinicaltrials/study/nct06501443*

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