Intravascular Imaging Study of the Effect of Inclisiran on Plaque in Patients With Acute Myocardial Infarction

Last Update: Mar 17, 2025

A Multi-Center, Randomized, Open-label, Parallel, Controlled Phase IV Clinical Trial to Evaluate the Effect of Inclisiran on Coronary Atherosclerotic Plaque in Patients With Acute Myocardial Infarction and Elevated Low-density Lipoprotein Cholesterol

ClinicalTrials.gov Identifier:

NCT06372925

Novartis Reference Number:CKJX839A1CN04

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 to evaluate the effect of Inclisiran on coronary atherosclerosis using intravascular ultrasound (IVUS) and optical coherence tomography (OCT) in patients with acute myocardial infarction and elevated low-density lipoprotein cholesterol (LDL-C). This study will be a multi-center, randomized, parallel-group, open-label, phase 4 study. Participants will be approximately 318 Chinese adults diagnosed with new-onset STEMI/NSTEMI and elevated LDL-C (LDL-C \> 1.8 mmol/L if on stable dose of statin (with or without ezetimibe) for ≥ 4 weeks; LDL-C \> 2.6 mmol/L if not on stable dose of statin (with or without ezetimibe) for ≥ 4 weeks). Participants will be 1:1 randomized to investigational group (Inclisiran 284mg + 20mg atorvastatin) or control group (20mg atorvastatin) for 360 days. Participants and investigator will be unblinded to the identity of the treatment from the time of randomization. Independent Review Committee (IRC) staff performing the study assessments (IVUS and OCT analysis) will be blinded to the identity of the treatment from the time of randomization until final database lock.

Condition

Plaque, Atherosclerotic

Phase

Phase4

Overall Status

Recruiting

Number of Participants

318

Start Date

Jul 12, 2024

Completion Date

Jun 24, 2026

Gender

All
Age(s)
18 Years - 75 Years (Adult, Older Adult)

Interventions

Drug

atorvastatin

20mg atorvastatin PO
Drug

inclisiran

Inclisiran 284mg SC
Procedure

IVUS/OCT

performed the IVUS/OCT at baseline and Day 360

Eligibility Criteria

Inclusion Criteria:

1. Male or female ≥ 18 and ≤ 75 years of age.
2. Acute myocardial infarction (STEMI ≤ 24h/NSTEMI ≤ 72h of onset of symptoms) with planned PCI.
3. At least 1 major, non-infarct-related coronary artery ("target vessel") meet all of the following criteria judged by the investigator:

1) Presence of atherosclerotic plaque with ≥ 20% and ≤ 50% diameter stenosis by coronary angiography.

2) Target vessel deemed to be accessible to imaging catheters and suitable for intravascular imaging in the proximal (50 mm) segment ("target segment") 3) Target vessel is suitable for IVUS and OCT evaluation. 4) Not have undergone previous PCI within target vessel. 5) Not be a bypass graft or a bypassed native vessel. 4. Rapid LDL-C test value at screening period of:

1. LDL-C \> 1.8 mmol/L if on stable dose of statin (with or without ezetimibe) for ≥ 4 weeks upon signing ICF.
2. LDL-C \> 2.6 mmol/L if not on stable dose of statin (with or without ezetimibe) for ≥ 4 weeks upon signing ICF.

5. Written informed consent must be obtained.

Exclusion Criteria:

1. Familial hypercholesterolemia or secondary hypercholesterolemia.
2. Clinically instable AMI (hemodynamic or electrical instability).
3. Left main disease, defined as ≥ 50% diameter stenosis of the left main coronary artery by coronary angiography.
4. Three-vessel disease, defined as ≥ 70% diameter stenosis of 3 major epicardial coronary vessels or in

major branches of these arteries by coronary angiography.
5. Have a plan for interventional procedure within 12 months after signing ICF.
6. Known intolerance to Atorvastatin OR known statin intolerance.
7. Patients already on high-intensity statin including atorvastatin 40 or 80 mg or rosuvastatin 20 mg upon signing ICF.
8. Patients not suitable for IVUS/OCT evaluation (e.g., significant calcification , etc) judged by the investigator.
9. Patients qualify for coronary artery bypass surgery at screening and history of coronary artery bypass surgery.
10. Cardiac disorders:

1) Uncontrolled cardiac arrhythmia, defined as recurrent and symptomatic ventricular tachycardia or atrial fibrillation with rapid ventricular response not controlled by medications in the past 3 months prior to screening; 2) Pacemaker or ICD in situ; and/or 3) Uncontrolled severe hypertension with systolic blood pressure \>180 mmHg or diastolic blood pressure \>110 mmHg prior to randomization despite antihypertensive therapy.

11. Rapid lipid test triglyceride (TG) level \> 400mg/dL (4.5 mmol/L) at screening.

12. Active liver disease defined as any known current infectious, neoplastic, or metabolic pathology of the liver or unexplained elevations in alanine aminotransferase (ALT), aspartate aminotransferase (AST), \> 3x the upper limit of normal (ULN), or total bilirubin \> 2x ULN before the randomization.

13. Estimated glomerular filtration rate (eGFR) \< 30 mL/min/1.73m2(Calculated according to the modified MDRD equation).

14. Severe concomitant non-cardiovascular disease that carries the risk of reducing life expectancy to less than 2 years.

15. Previous (within 90 days before randomization), current or planned treatment with a PCSK9 monoclonal antibody (mAb).

16. Previous exposure to Inclisiran or any other non-mAb PCSK9-targeted therapy 2 years prior to randomization.

17. Participation in another investigational device or drug study currently, or within 5 half-live (if drug) or 30 days whichever is longer, prior to randomization.

18. History of hypersensitivity to any study drug or its excipients. 19. Any uncontrolled or serious disease, or any medical or surgical condition, that may either interfere with participation in the clinical study and/or put the participant at significant risk according to investigator's judgment.

20. Pregnant or nursing (lactating) women. 21. Women of child-bearing potential, unless they are using effective methods of contraception during study treatment.

22. Any conditions that according to the investigator could interfere with the conduct of the study.

China

Novartis Investigative Site

Recruiting

Harbin,Heilongjiang,150086,China

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/nct06372925*

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