NOVARTIS

Clinical Trial
Results Summary

A clinical trial to learn more about the effects of KJX839 in Chinese participants with primary hypercholesterolemia or mixed dyslipidemia

Thank you!

Thank you to the participants who took part in the clinical trial for high levels of bad cholesterol in the blood (**primary hypercholesterolemia**), or abnormal levels of fats in the blood (**mixed dyslipidemia**). Every participant helped the researchers learn more about the trial drug **KJX839**, also called **inclisiran**.

Novartis sponsored this trial and believes it is important to share what was learned from the results of this trial with the participants and the public. We hope this helps the participants understand their important role in medical research.

Trial information

Trial number: CKJX839D12305

Novartis drug studied: **KJX839**, also called **inclisiran**

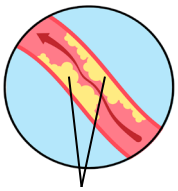
Sponsor: Novartis

If you were a participant and have any questions about the results, please talk to the doctor or staff at the trial site.

This summary only shows the results of a single clinical trial. Other clinical trials may have different results.

What was the main purpose of this trial?

The purpose of this trial was to learn more about the effects of **KJX839** as a single therapy in adult Chinese participants with high levels of bad cholesterol (primary hypercholesterolemia) or abnormal levels of fats in the blood (mixed dyslipidemia). To find this out, researchers compared the effects of **KJX839** to **placebo**.



Bad cholesterol in blood vessels

Primary hypercholesterolemia is a condition in which there are high levels of bad cholesterol in the blood.

Mixed dyslipidemia occurs when a person has abnormal levels of fats in the blood, which include high bad cholesterol, low good cholesterol, and high triglyceride levels in the blood.

Both primary hypercholesterolemia and mixed dyslipidemia can increase the risk of heart attack or stroke. These conditions are life-threatening and are collectively called atherosclerotic cardiovascular disease (**ASCVD**).

Cholesterol is a fat-like substance present in the blood. There are two main types of cholesterol:

- LDL cholesterol, or "**bad**" cholesterol, which can build up in blood vessels
- HDL cholesterol, or "**good**" cholesterol, which helps remove other types of cholesterol and protects the heart

Triglyceride (another fat-like substance in the blood) is the main form of stored fat in the body.

KJX839, also called **inclisiran**, is a drug approved for the treatment of high levels of bad cholesterol in the blood. It works by stopping the liver from releasing too much PCSK9, a protein that can slow down how the body removes bad cholesterol from the blood. If blood levels of PCSK9 go down, levels of bad cholesterol should also go down.

Trial drug
KJX839, also called inclisiran
Pronounced as
IN-kli-SIR-an

In this trial, researchers wanted to check if **KJX839** can lower bad cholesterol levels in Chinese participants with high levels of bad cholesterol who are at risk of developing ASCVD.

A **placebo** looks like the trial drug but does not have any drug in it. Using a **placebo** helps researchers better understand the effect of a trial drug.

The trial's purpose was to answer these main questions:

- Did **KJX839** lower the bad cholesterol levels after 5 months of treatment as compared to **placebo**?
- What medical problems, also called adverse events, happened during this trial?

  Adverse events reported in this trial were any sign or symptom that participants had during the trial. Adverse events **may** or **may not** be caused by treatments in the trial.

How long was this trial?

The trial began in July 2023 and ended in October 2024. Participants were in the trial for about 1 year.

This trial was designed to have 2 parts:

- During **Part 1**, participants received either **KJX839** or **placebo** to learn more about the effects of **KJX839** in reducing bad cholesterol levels in participants over the first 6 months of the trial.
- During **Part 2**, participants received **KJX839** to further assess its long-term effects for an additional 6 months.

When the trial ended, researchers created a report of the trial results. This summary is based on that report.

Who was in this trial?

207 participants from China with **primary hypercholesterolemia** or **mixed dyslipidemia** received treatment in this trial – 86 men and 121 women. Participants' ages ranged from 23 to 75 years. Their average age was 48 years. All participants were Asian by race.

The participants could take part in this trial if they:

- were between 18 and 75 years of age and had high levels of bad cholesterol and triglycerides in their blood
- were considered at low or moderate risk of ASCVD
- had not taken **KJX839** or any similar treatment that targets PCSK9 within 2 years before the trial started
- had neither taken any lipid-lowering treatment within 3 months before the trial, nor planned to take such a treatment during the trial

What treatments did the participants receive?

The treatments in this trial were:

KJX839: Participants received a dose of 300 milligrams (mg) of **KJX839** as an injection under the skin on Day 1 and at Months 3, 6, and 9.

Placebo: Participants received **placebo** in the same way as **KJX839** on Day 1 and at Months 3 and 6.

Researchers used a computer to randomly assign participants to their treatments.

During **Part 1** of the trial, none of the participants, researchers, or trial staff knew what treatment the participants were receiving. Some trials are done this way because knowing what treatment the participants receive can affect the results of the trial. Doing a trial this way helps to make sure that the results are looked at with fairness across all treatments.

During **Part 2** of the trial, all participants, trial doctors, and trial staff knew what treatment the participants were receiving.

What happened during this trial?

Before treatment

Up to 2 weeks

The trial staff checked to make sure the participants could be in this trial.

During treatment

Up to 1 year

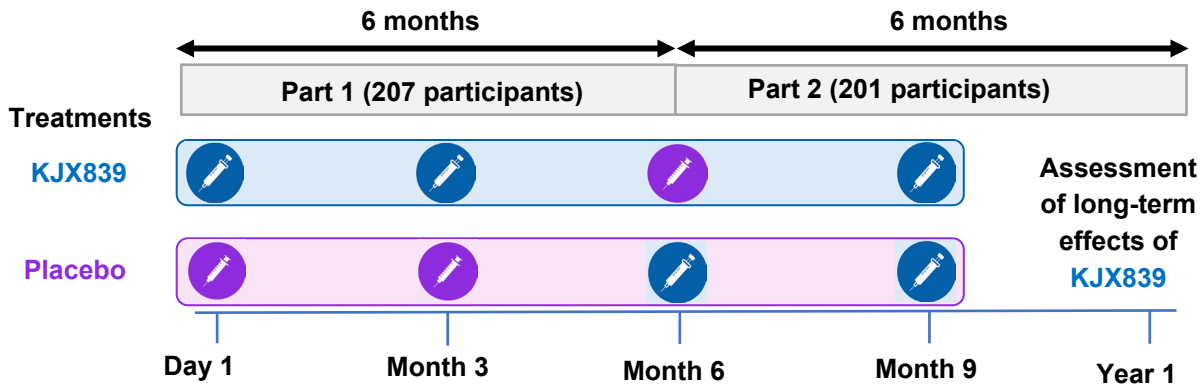
Part 1 (6 Months)

207 participants were randomly divided into 2 groups to receive either **KJX839** or **placebo** injections.

Part 2 (6 Months)

201 participants entered and continued treatment in this part.

At the start of **Part 2**, participants who were on **KJX839** in **Part 1** received **placebo**, and those who were on **placebo** in **Part 1** received **KJX839**. At Month 9, all participants received a **KJX839** injection.



During the trial, researchers took the participants' blood samples and did overall health check-ups at different time points to learn about the effects and safety of **KJX839**.

After treatment

Up to 3 months

Trial staff checked participants' general health for any medical problems up to 3 months after the last dose of trial treatment.

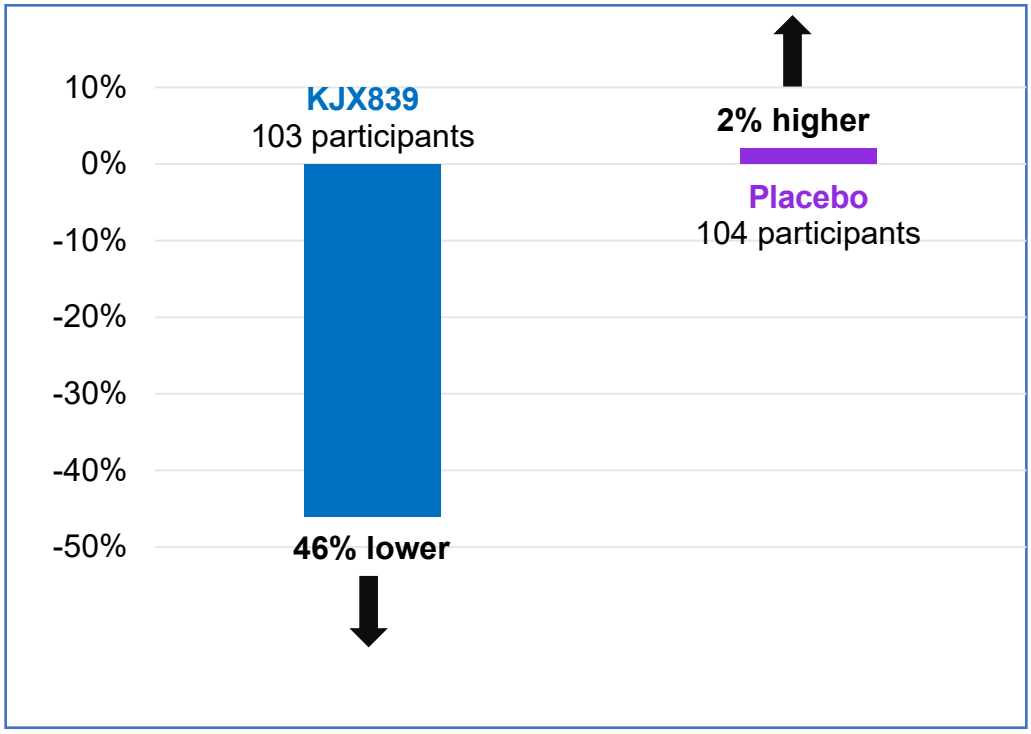
What were the main results of this trial?

Did KJX839 lower the bad cholesterol levels after 5 months of treatment as compared to placebo?

After 5 months of treatment, researchers found that participants who received **KJX839** had an average decrease of **46%** in bad cholesterol levels, and those who received **placebo** had an average increase of **2%** in bad cholesterol levels.

To find this out, the researchers took participants' blood samples and measured the level of bad cholesterol in participants' blood before treatment and after 5 months of treatment. Then, they calculated the change in the bad cholesterol levels and compared it between the participants who received **KJX839** and those who received **placebo**.

Change in bad cholesterol levels after 5 months of treatment



What were the other results of this trial?

Did KJX839 lower the bad cholesterol levels after 11 months of treatment?

Results were available for 103 participants who were randomly assigned to receive **KJX839** in both parts of the trial.

Researchers found that participants in the **KJX839** group had a 45% reduction in their bad cholesterol levels after 11 months of treatment.

What medical problems, also called adverse events, happened during this trial?

Trial doctors keep track of all medical problems, also called **adverse events**, that happen in trials. They track adverse events even if they think the adverse events are not related to the trial treatments. Many trials are needed to know if a drug or treatment causes an adverse event.

This section is a summary of the adverse events that happened from the start of the treatment up to 3 months after the last dose of **KJX839**.

An **adverse event** is:

- Any **sign or symptom** that the participants have during a trial
- Considered **serious** when it is life-threatening, causes lasting problems, the participant needs hospital care, or results in death

Adverse events **may** or **may not** be caused by treatments in the trial.

- Most participants (166 out of 207) had adverse events.
- 11 participants had adverse events that were considered serious.
- None of the participants died or left the trial due to an adverse event.

The researchers concluded there were no new safety concerns for **KJX839** in this trial.

What serious adverse events did the participants have?

The following serious adverse events happened during the trial. Each event happened in one participant only, with some participants experiencing more than 1 event.

Part 1		Part 2	
KJX839 103 participants	**Placebo** 104 participants	**KJX839 to KJX839** 100 participants	**Placebo to KJX839** 101 participants
• **Feeling dizzy in a certain position** (Vertigo positional) • **Heart attack** (Acute coronary syndrome) • **Pinched neck nerve** (Cervical radiculopathy) • **Shoulder tendon injury** (Rotator cuff syndrome) • **Slipped disc** (Intervertebral disc protrusion) • **Stroke** (Cerebrovascular accident) • **Thyroid cancer**	• **COVID-19 infection** (COVID-19) • **Lung Infection** (Bronchitis) • **Swollen blood vessels in or around the anus** (Hemorrhoids)	• **A bulge in the groin, the crease between the belly and the upper leg** (Inguinal hernia)	• **Feeling dizzy** (Vertigo) • **Swelling and infection of the appendix** (Appendicitis)

What other adverse events (not including serious) did the participants have?

The table below shows the most common other adverse events.

	Part 1		Part 2	
	KJX839 103 participants	**Placebo** 104 participants	**KJX839 to KJX839** 100 participants	**Placebo to KJX839** 101 participants
High levels of a liver enzyme called alanine aminotransferase (Alanine amino-transferase increased)	**6 of 103** 6%	**3 of 104** 3%	**5 of 100** 5%	**4 of 101** 4%
High levels of a muscle enzyme, called creatine phosphokinase, in the blood (Blood creatine phosphokinase increased)	**7 of 103** 7%	**6 of 104** 6%	**6 of 100** 6%	**7 of 101** 7%
High levels of sugar in the blood (Blood glucose increased)	**10 of 103** 10%	**7 of 104** 7%	**4 of 100** 4%	**3 of 101** 3%
Infection of the nose and throat (Upper respiratory tract infection)	**25 of 103** 24%	**17 of 104** 16%	**14 of 100** 14%	**9 of 101** 9%

What was learned from this trial?

Researchers learned about the effects of **KJX839** as a single therapy in adult Chinese participants with high levels of bad cholesterol (**primary hypercholesterolemia**) or abnormal levels of different types of fats in the blood (**mixed dyslipidemia**).

Researchers concluded that:

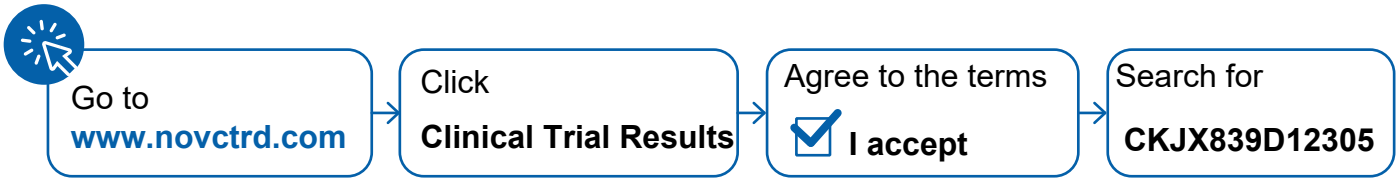
- after 5 months of treatment, participants who received **KJX839** showed a reduction, and those on **placebo** showed an increase in the bad cholesterol levels in their blood
- after 11 months of treatment, participants who received **KJX839** had a 45% reduction in their bad cholesterol levels
- there were no new safety concerns with the use of **KJX839** in the trial

When this summary was written, there were ongoing trials with **KJX839** in people with primary hypercholesterolemia or mixed dyslipidemia.

Where can I learn more about this trial?

More information about the results and adverse events in this trial can be found in the scientific summary of the results available on the Novartis Clinical Trial Results website, **www.novctrd.com**.

Follow these steps to find the scientific summary:



For more information about this trial, go to any of these websites:

- clinicaltrials.gov – search using the number **NCT05888103**

Other trials of **KJX839** may appear on the public websites above. When there, search for **KJX839** or **inclisiran**.

Full clinical trial title: A 6 month randomized, double-blind, placebo-controlled study followed by a 6 month open-label extension to assess the efficacy and safety of inclisiran as monotherapy in Chinese adults with low or moderate ASCVD risk and elevated low-density lipoprotein cholesterol

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