



**1 DOSE** • Could it help conquer  
• high cholesterol?

---

**Be Part of the Heart-2 Study**



**heart-2**



# heart-2

## Can you participate?

You may be eligible to take part if you\*:



18-70

Are 18-70 years old.



Have been diagnosed with:

HeFH – an inherited condition causing high LDL-C,  
and/or

Premature CAD – defined as serious heart disease occurring before  
the age of 65 in women or 55 in men.



Have LDL-C levels that remain too high despite taking  
cholesterol-lowering medicines.



Are not taking a PCSK9 inhibitor medication.

\*Additional eligibility criteria apply

# About the Heart-2 Study

The Heart-2 study is a clinical trial open to people with heterozygous familial hypercholesterolemia (HeFH) and/or premature coronary artery disease (CAD) who require additional lowering of low-density lipoprotein cholesterol (LDL-C). The purpose of the Heart-2 study is to assess the safety and tolerability of the investigational medicine called VERVE-102, and see if it can help lower LDL-C levels with a single dose.



The investigational medicine is designed to permanently turn off production of the PCSK9 protein in the liver. It does this by inactivating the *PCSK9* gene using an approach called gene editing. This may reduce LDL-C levels in the bloodstream.

Because gene editing is expected to be a permanent change, it is given just one time through an intravenous (IV) infusion (this means it will be administered into a vein).

---

## What will the study involve?

Participants will be in the Heart-2 study for at least one year after receiving the investigational medicine. After the study is over, you will be asked to join a second, long-term follow-up study to help researchers understand the safety of VERVE-102 over a longer period. The study doctor will share the details of this with you.

# The study has three periods:

## **1** Screening Period (up to 3 months)

You will attend screening appointments to determine your eligibility for the trial. During this time, several tests will be performed, including taking blood samples and performing physical examinations.

- You will visit the study site two or more times to determine whether the study is right for you. If you are eligible, you will have the option to join the study.
  - The screening visits need to occur within a three month period.
- 

## **2** Study Treatment Period (about 4 days)

If you qualify and decide to participate, the study treatment period will be four days, including two or three overnight stays, during which:

- You will receive a single dose of the investigational medication as an IV infusion in your arm.
  - The study team will monitor your health and conduct assessments similar to the screening period to check how well you tolerate the investigational medicine.
  - If needed, your stay may be extended for additional monitoring.
- 

## **3** Follow-up Period (about 1 year)

- There will be 10 scheduled follow-up visits over the year after receiving the investigational medication to continue to monitor your health including the end-of-study visit.
- After the end-of-study visit, you will transition into a long-term follow-up study to monitor your safety and cholesterol levels. Many of these visits can be done from home.



## Why might you consider participation?

Millions of people around the world have been impacted by cardiovascular disease caused by high levels of LDL-C. Many people make lifestyle changes and take cholesterol-lowering medications but still have high LDL-C levels, putting them at increased risk of having a heart attack or stroke. Lowering LDL-C is one of the best ways to reduce these risks.

By taking part in the Heart-2 study, you will receive VERVE-102, which may permanently reduce LDL-C levels. However, it is important to note that the safety and effectiveness of VERVE-102 are still being studied.

---

The investigational medicine may be able to help lower your LDL-C levels for many years or possibly the rest of your life, with a single dose.

# Additional information about the Heart-2 study

---



The study team will explain the possible benefits and risks of taking part in the Heart-2 study.



If you choose to take part in the study, you can stop participating at any time.



You will be reimbursed for your time participating in this study.



You will be reimbursed for travel costs or other expenses during your participation.



The study medication and study-related tests will be provided at no cost to study participants.



A team of study doctors and nurses will monitor your health carefully during the study.



The study has been cleared by an Institutional Review Board/Ethics Committee and national health authority, which protects the rights, safety, and well-being of participants.



## How do you get more information?

To find out more, please visit the study website

[Heart2Study.com](https://Heart2Study.com)

Study participation is voluntary. By contacting us, you are under no obligation to take part in the study.

