Cardiovascular
Clinical Trial

VICTORION-1 PREVENT

Information about the VICTORION-1 PREVENT study

NOVARTIS | Reimagining Medicine

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Is your high cholesterol level increasing your risk of having a major cardiovascular event?

If you have high levels of low-density lipoprotein (LDL) cholesterol (also known as ‘bad’ cholesterol) – or other risk factors such as diabetes, high blood pressure or obesity – you are more likely to experience a heart attack or stroke. Smoking, being inactive and getting older also increase risk.

Consistent high levels of LDL cholesterol in the blood can cause the gradual buildup of thick and fatty deposits (or plaques) on the walls of the arteries. Over time, plaques can build so much that arteries can become narrowed. Narrowed arteries can block blood flow, which can lead to a heart attack or stroke.

Why is the VICTORION-1 PREVENT study important?

LDL cholesterol should be kept below a certain level. If levels get too high, making changes to our diet and lifestyle is usually recommended, but modifying lifelong habits can be challenging. Statins can also help to reduce cholesterol levels, although people can sometimes find it difficult to adhere to taking daily medications.

The VICTORION-1 PREVENT study will assess if an investigational medication can prevent cardiovascular events (such as heart attacks, strokes, procedures to improve blood flow, and death) in the future by lowering LDL cholesterol in the blood.

How does the investigational medication work?

The liver has special receptors that help to regulate LDL cholesterol levels. They work by ‘grabbing’ excess LDL cholesterol out of the blood and passing it to the liver to be broken down. Our bodies also make a protein called PCSK9, which breaks down the LDL receptors. The fewer receptors we have, the less LDL cholesterol can be broken down.

The investigational medication works by blocking the production of PCSK9 protein, which then allows the body to remove more LDL cholesterol. So, we want to see if an investigational medication can prevent cardiovascular events in adults who are at high risk by reducing their LDL cholesterol.

What is a clinical study?

A clinical study (also known as a clinical trial) is a carefully controlled scientific research study that helps scientists to find:

- Potential new medications
- New versions of medications already being used
- New uses for medications already being used

Millions of people all around the world take part in clinical studies every year. In fact, every medication you have ever taken will have first been investigated in a clinical study.

It is important to note that all clinical studies must be approved by country regulatory boards and ethics committees before they can begin. This is done to protect the safety and rights of the study participants by reviewing and approving the study's 'protocol' (a plan that explains how the study should be conducted and which procedures have to be performed and when) and other relevant study documents and procedures.

Who can take part in the VICTORION-1 PREVENT study?

We are looking for 14,000 people from around the world to take part. Each participant must:

- Be 40 to 79 years of age
- Have high LDL cholesterol levels
- Not have experienced a major cardiovascular event
- Be at high risk for a major cardiovascular event in the future

Do not worry if you are not sure about whether you meet these criteria at the moment. We will assess each potential participant during a screening visit to make sure that they are a good fit for the study. For now, simply read this brochure and think about whether you might like to take part. And thank you for your interest in this important study.

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What will taking part in the study involve?

The study is expected to last for approximately 6 years. Your participation in this study will likely be between 3 and 5 years, depending on when you enter the study. If you have any questions about this, the study team can explain this further.

The study will consist of the following:

Screening period

Up to 14 days

Assessments will be carried out to check if you can join the study.

Double-blind treatment period

If you are eligible, you will receive your assigned study medication (the investigational medication or placebo) and attend study visits for assessments on Day 1, Day 90 (Month 3), and then every 6 months until the end of the study.

End of study visit

Once the study is complete, you will be asked to come in for one final visit so that the study team can check on your general health and cardiovascular risk. You will not be given the study medication on this visit.

Follow-up call

Around 30 days after the end of study visit, the study team will contact you by telephone to check on your health and well-being.

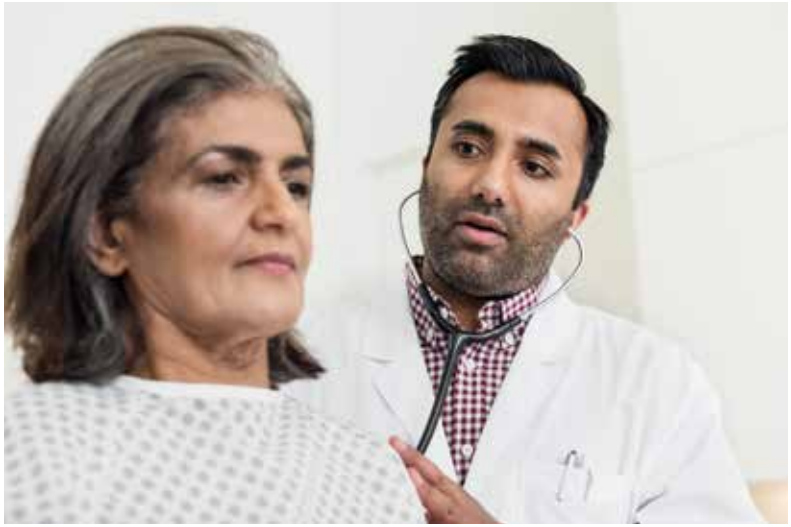
Which study medication will I receive?

You will be randomly assigned (i.e., by chance, like the flip of a coin) to one of two groups by a computer. You have a 50% chance (1 in 2) of receiving the investigational medication and a 50% chance of receiving placebo. A placebo looks like the investigational medication but does not contain any active ingredients. We use a placebo to be sure that any effects that happen are actually caused by the investigational medication and not some other factor(s) and/or chance.

Both the investigational medication and the placebo are given by a healthcare professional as a subcutaneous (under the skin) injection. After your first dose, you will be given a second dose after 3 months, and then a dose every 6 months until the end of the study.

What does ‘double-blind’ mean?

This study is ‘double-blind,’ which means that neither you nor the study team will know whether you have been assigned to the investigational medication or placebo. We do this so that we can be sure that any differences seen are due to the investigational medication and not some other factor.



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Frequently asked questions

How will my health be monitored?

During this study, participants will attend the study centre around once every 6 months. At study centre visits, participants will undergo assessments such as vital signs (measurement of blood pressure and heart rate), blood samples and urine samples to monitor their health. These assessments will vary from visit to visit.

Can I continue taking my current medications during the study?

Throughout the study, continue to take your statin – type and dose – as prescribed by your regular doctor or study doctor. Tell the study doctor about any other medications you are currently taking. Do not start taking any new medications or changing the dose of current ones without talking to the study doctor first.

Can I get my cholesterol tested while on the study?

If you get your cholesterol tested by your regular doctor while on the study, it is important that **neither you nor the study team are told the results**. If you accidentally find out your LDL cholesterol level, please do not share this information with the study team. This ensures that the study results are not influenced by any other information. Throughout the study, your cholesterol will be monitored regularly by our central laboratory. The study team will be notified if you need to adjust your medication.

What are the potential benefits of taking part?

Taking part in the study may not benefit you directly, but we may learn new things that could help treat people in the future. You may also benefit from reducing your risk of having a cardiovascular event and/or lowering of your LDL cholesterol, although this cannot be guaranteed.

We can, however, guarantee close monitoring of your cardiovascular risk with biannual visits with the study team. You will also receive education on cardiovascular risk reduction through lifestyle modifications (for example, physical exercise, weight control, healthy diet), as well as help adhering to your statin medication (for those who are taking statins).

What are the potential risks of taking part?

There may be side effects (or risks) from the study medication that we do not yet know about and from some of the assessments in the study. You should tell the study team if you have any complaints or side effects, or had any other doctor visits or hospitalisations outside the study. The most common side effect of the study medication is injection-site reactions (local skin reactions at the injection site), occurring in fewer than 10% of participants. As with any medication, it is possible that you may have an allergic reaction to the study medication. However, no allergic reactions were seen in three large previous clinical studies.

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How can I learn more?

If you have any questions, or for more information, please contact the study team using the details below.

Contact name:

Study site:

Address:

Telephone:

Email:

Notes:

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