is safe and effective. These studies may help doctors find new ways to help prevent, detect, or treat health problems.

Participant safety is the priority. There are rules in place to help protect the rights, safety, and well-being of people who volunteer for clinical research studies. These rules are put in place to make sure studies follow strict scientific and ethical guidelines.

Before a clinical research study can begin, a review board or ethics committee must review the study. In the U.S., this group is called an IRB or Institutional Review Board. In other countries, this group is called an EC or Ethics Committee. IRBs and ECs are made up of doctors, scientists, and members of the community.

Are there risks?

There may be some risks and discomforts associated with the investigational medication and medical assessments. The study doctor will go over the potential risks and benefits of this clinical research study and answer your questions.

If you decide to participate:

- You will receive the study treatment and all study-related medical care at no cost
- Your cholesterol and overall health will be closely monitored by a study doctor
- You may be eligible to be reimbursed for study costs incurred such as travel

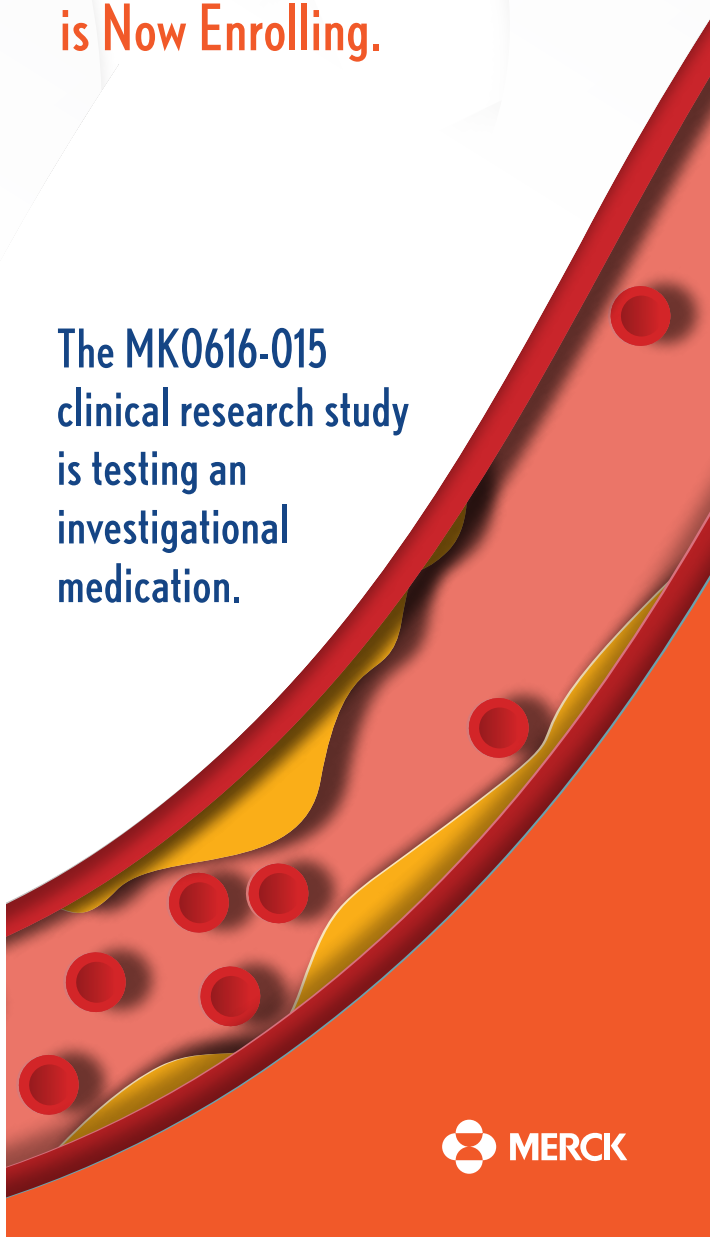
For more information, including the possible risks and benefits of being in this study, please contact:

MERCK

MK0616-015_Participant Recruitment Brochure_V1_15JUN2023

A Clinical Research Study for Adults Who Have High CHOLESTEROL is Now Enrolling.

The MK0616-015 clinical research study is testing an investigational medication.



MERCK

About this clinical research study

This clinical research study is testing an investigational medication in adults who have high cholesterol and have had or are at risk of having a major cardiovascular event such as a heart attack or stroke.

Researchers want to learn:

- How the investigational medication works to lower cholesterol compared to a placebo, which looks like the investigational medication but does not contain active ingredients
- The safety of the investigational medication
- If the investigational medication can reduce cardiovascular events

You may help researchers learn more about the investigational medication and treating high cholesterol.

Do I qualify for this clinical research study?

You may be able to take part in this study if you are at least 18 years of age, are taking cholesterol medication with or without supplements to control your cholesterol, and have had a cardiovascular event, such as one of the following:

- Heart attack
- Stroke
- Procedure to reopen a blocked artery in your neck or legs
- Amputation due to a blocked artery

You may also be eligible if you are age 50 or older, taking cholesterol medication with or without supplements to control your cholesterol, and are considered at high risk for a major cardiovascular event because you have health concerns such as blockages in 2 or more arteries. Or you are 60 or older and have risk factors such as diabetes mellitus or high blood pressure.

You must continue taking your cholesterol medication and/or supplements while you are in the study. There are additional requirements that must be met in order to take part in this study.

What will happen during this clinical research study?

If you qualify and decide to take part in this study, you will visit the study site for medical tests and assessments about 6 times and have a telephone call with the study team at least once during the first year of the study.

In the years after the first year, you will visit the study site at least 2 times and have 2 telephone visits per year.

The length of time you will participate in the study is determined by when you join the study. The average time is about 4 and a half years.

What is the investigational medication?

The investigational medication is a type of cholesterol medication called a PCSK9 inhibitor. The currently approved PCSK9 inhibitors are taken as an injection, but the PCSK9 inhibitor being tested in this study is a tablet that you swallow.

Will I receive the investigational medication?

Participants will be randomly assigned to receive the investigational medication or a placebo. You will have an even 50-50 chance of receiving the investigational medication or a placebo. Neither you nor the study team will know whether you've been assigned to the investigational medication or a placebo.

What activities are involved in this study?

Medical tests include physical exams, blood samples, vital signs (heart rate and blood pressure), and an electrocardiogram (ECG, which examines your heart function).

Participants will be encouraged to follow a low-cholesterol diet and a suitable exercise routine while in the study. They will also be required to fast (no food or drink for at least 8 hours, water is ok) before taking the study treatment each day, and to wait at least 30 minutes after taking the study treatment before eating any food or drinking any beverages (except water). They will also be expected to fast before most of the study visits.

What is clinical research?

A clinical research study tries to answer questions about how medications work in the people who take them. Researchers run studies to test whether an investigational medication