

Protocol Plain Language Summary

A clinical study of MK-0616 for people with high amounts of low-density lipoprotein cholesterol (MK-0616-017)

Protocol title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MK-0616 in Adults With Heterozygous Familial Hypercholesterolemia

Why is this study needed?

Researchers are looking for new ways to lower the amount of **low-density lipoprotein cholesterol (LDL-C)** in a person's blood. LDL-C is sometimes called "bad cholesterol." Cholesterol is a type of fat in the blood. Some people have a form of high cholesterol that runs in families called **Heterozygous Familial Hypercholesterolemia (HeFH)** that causes high LDL-C levels. Having too much LDL-C can cause cholesterol or fatty deposits to stick to the walls of arteries (called plaque). This causes the arteries to narrow, which means less blood can flow through them. Lowering a person's LDL-C can lower their chances of events such as heart attacks, stroke, and death.

MK-0616 (the study medicine) is in a class of medicines that have been shown to reduce LDL-C. MK-0616 is different from the other medicines in this class because it is taken as a tablet and not an injection. The purpose of the study is to learn if **MK-0616** works better than **placebo** to lower the amount of LDL-C in people with **HeFH**. Researchers also want to learn about the safety of MK-0616, including how well people tolerate (manage) it.

Who will take part in this study?

About 270 people will be in this study. They will be 18 years old or older and:

- Have HeFH
- Currently taking medications to reduce high cholesterol

People with a history of certain kinds of heart disease or other specific medical conditions may not be able to be in this study.

What treatments are being given?

People will be assigned by chance to take one of these by mouth once a day as a tablet for about a year:

- **MK-0616**
- **Placebo:** which looks like the study medicine but has no study medicine in it. Researchers use a placebo to better understand the actual effects of the study medicine.

People will take their treatment on an empty stomach in the morning and not eat for 30 minutes afterwards.

How is this study designed?

People will have a 2 out of 3 chance of getting MK-0616, and a 1 out of 3 chance of getting placebo. This means that twice as many people will take MK-0616 than placebo.

Neither the people in the study nor the researchers will know if a person gets MK-0616 or placebo (called a double-blind study).

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During the study, people may have blood tests, tests to measure electrical activity in the heart (called electrocardiogram or ECG) and have physical examinations. People may be in this study for up to about 16 months.

What are the goals of this study and how will they be measured?

Main goals	How they will be measured
To learn if MK-0616 works better than placebo to lower LDL-C	The change in the amount of LDL-C in a person's blood after 6 months of treatment
To learn about the safety of MK-0616 and how well people tolerate MK-0616	The number of people who: <ul style="list-style-type: none"> • Had an adverse event (AE) – An AE is a health problem that happens or worsens during a study • Stopped treatment due to an AE
Other goals	How they will be measured
To learn if MK-0616 works better than placebo to lower LDL-C	The change in the amount of LDL-C in a person's blood after 1 year of treatment
To learn if MK-0616 works better than placebo to lower all cholesterol that isn't considered "good." This is called non-high-density lipoprotein cholesterol (non-HDL-C) and includes LDL-C.	The change in the amount of non-HDL-C in a person's blood after 6 months of treatment
To learn if MK-0616 works better than placebo to lower apolipoprotein B (ApoB) and lipoprotein (a) (Lp(a)) . ApoB and Lp(a) are proteins that carry cholesterol in the blood.	The change in the amount of ApoB and Lp(a) in a person's blood after 6 months of treatment
To learn how well MK-0616 works to lower LDL-C compared to placebo	The number of people whose LDL-C levels lower by half after 6 months of treatment. This will include people whose LDL-C is lowered to: <ul style="list-style-type: none"> • Less than 70 milligrams of LDL-C per deciliter of blood (mg/dL) • Less than 55 mg/dL

What are the possible benefits and risks?

People in this study may not benefit from treatment. This study has an external group of experts that oversees the overall risk and benefit. If this group of experts decides that the study treatment is not safe, the study can be stopped.

More information about benefits and risks may be found in the Investigator's Brochure, Protocol, and Informed Consent documents.