

Protocol Plain Language Summary

A clinical study of MK-0616 for people with high amounts of low-density lipoprotein cholesterol (MK-0616-013)

Protocol title: A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of MK-0616 in Adults With 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 a person's blood. 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 a person's blood. 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 2,760 people with a history of high cholesterol will be in this study. They will be 18 years old or older and:

- At risk of having heart attacks, strokes, or other events that happen due to plaque buildup in the arteries
- May be taking treatment to reduce high cholesterol, except a treatment in the same class as MK-0616

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 studied?

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 then not eat for 30 minutes after taking their treatment.

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

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people in the study nor the researchers will know if a person gets MK-0616 or placebo (called a double-blind study).

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 1 year and 2 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 safety 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	The number of people who have the level of LDL-C in their blood lowered 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 or may not benefit from the 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 or does not show benefit, the study can be stopped.

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