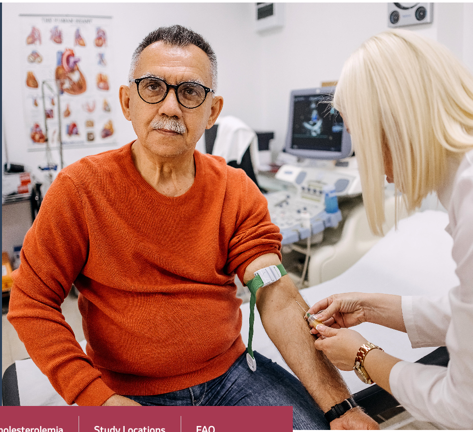
Trials > Cardiovascular diseases > MK-0616 Cardiovascular Outcomes ...

CORALreef Outcomes



Do you have high LDL? If so, you may be eligible for a research study

This study is evaluating an investigational drug to see whether it is safe and effective in reducing the risk of major adverse cardiovascular events in participants at high cardiovascular risk.

Explore Study Locations >

About the Study | How to Qualify | About Hypercholesterolemia | Study Locations | FAQ

● Recruiting   Print PDF   Email

About the CORALreef Outcomes Study

The CORALreef Outcomes study will test an oral investigational drug to see if it may safely and effectively lower the risk of major adverse cardiovascular events, such as a heart attack, a stroke, or heart disease in participants at high cardiovascular risk. This research study compares the investigational drug to a placebo (a placebo looks like the investigational drug but does not contain any active medicine). All participants will take an approved cholesterol medication in addition to the investigational drug or a placebo. The investigational drug is a tablet taken by mouth once a day.

Researchers want to:

- Study whether the investigational drug lowers LDL-C (cholesterol) and lowers the risk for other health incidents related to high cholesterol such as heart attack, stroke, or heart disease
- Learn about the safety of the oral investigational drug and any side effects

CLINICALTRIALS.GOV IDENTIFIER
NCT06008756

EU CT NUMBER
2022-502781-24

When you talk with your doctor or clinical trial team member, please have the trial identifier number available.

How to read clinical trials

Commitment to patient safety

View full study information on ClinicalTrials.gov

Discuss With Your Doctor or Research Team

Print this page with details about the study or email it to your doctor to discuss the research study during your next visit.

Get help talking with your doctor or research team

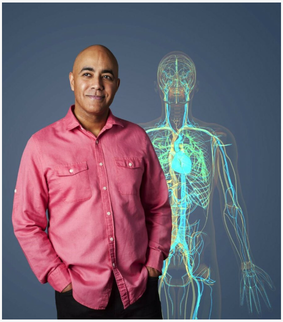
How to Qualify:

You may be able to take part in this research study if you:

- Are 18 years or older

- Have high cholesterol
- Have had, or are at risk of having, a serious health incident related to your high cholesterol (such as heart attack, stroke, or heart disease)
- Currently take medication for high cholesterol

There are more requirements to be in this research study. The study doctor will talk with you about all the requirements for the study to see if you may qualify.



If you qualify and decide to participate:

- You may receive the oral investigational drug and all study-related medical tests at no cost
- Your overall health will be monitored by a study doctor
- You may help researchers learn more about high cholesterol and the oral investigational drug

You will continue to take your current cholesterol medication, called a statin, during the research study.

Participation in the research study is voluntary, and you are free to leave the study at any time. Your privacy will be maintained throughout the study.

Explore Study Locations >

Key Study Facts

Study Duration

Length of study: The CORALreef Outcomes study lasts on average 4.5 years, up to 6 years.

Trial start and end dates

Trial start date	**October 9, 2023**
Estimated primary completion date	**November 29, 2029**
Estimated trial completion date	**November 29, 2029**

This research study has 3 parts:

1 Screening
(up to 60 days)

You will have medical tests to see if you qualify for the study. You will visit the study site 1 or more times.

2 Study Treatment Period
(4.5 years on average, up to 6 years)

You will take the investigational drug or a placebo in addition to your current prescribed cholesterol medication. During the first year of the study, you will visit the study site 5 times and have 1 phone visit. After that you will visit the study site 2 times and have 2 phone visits each year. The study will end when enough information has been collected about the effect of the investigational drug in reducing the risk of serious health incidents related to high cholesterol.

3 Follow-up
(about 8 weeks)

After you stop participating in the research study, you will have 1 follow-up phone visit.

Will I receive the investigational drug during the Study Treatment Period?

Participants will be randomly placed (assigned by chance) into 1 of 2 study treatment groups. You will have a:

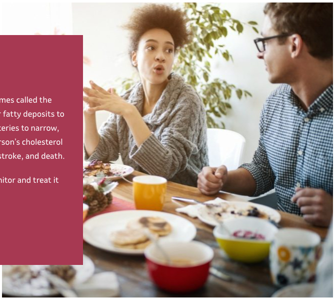
- 1 in 2 (50%) chance of receiving the investigational drug
- 1 in 2 (50%) chance of receiving a placebo

You will continue to take your current cholesterol medication throughout the study.

About High Cholesterol

Cholesterol is a type of fat in a person's blood. LDL-C is sometimes called the "bad cholesterol" and having too much 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 cholesterol may help lower their chances of events such as heart attacks, stroke, and death.

Since high cholesterol has no symptoms, it is important to monitor and treat it as needed to avoid more serious health complications.[1]



For Healthcare Professionals

The CORALreef Outcomes study is evaluating an oral investigational PCSK9-inhibitor (PCSK9i), called MK-0616, to see if it may reduce the risk of major cardiovascular events in adults with hypercholesterolemia and high-risk atherosclerotic cardiovascular disease (ASCVD), or who are at high risk for developing ASCVD.

Study Locations

Locations shown may have changed in some cases. Please call the number listed in the location results to confirm the nearest study site. Talk with a study site member for more information.

Search by location

Clalit health Services - Holon Medical Center

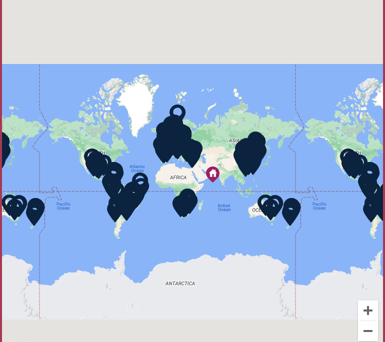
2315.05
miles

Holon
Israel
+972 5449182509
Get Directions

Sheba Medical Center

2315.85
miles

Ramat Gan
Israel
+972 3-530-2617
Get Directions



Frequently Asked Questions

Expand All | Collapse All

About the CORALreef Outcomes Study

Why is the CORALreef Outcomes study being conducted?

The CORALreef Outcomes study is being conducted to test an investigational drug in adults aged 18 years and older with high cholesterol. This research study will evaluate whether the oral investigational drug may safely and effectively lower cholesterol levels.

How do I decide if this research study is right for me?

Before you agree to participate, the study team will review all aspects of the research study with you. If you decide to take part, you will be given a document called an Informed Consent Form that provides, in writing, the research study's purpose, assessments, procedures, potential benefits and risks, and precautions. You will have the opportunity to ask questions and decide if participating is right for you.

What is a placebo?

A placebo looks like the investigational drug but does not contain any active medicine. In this research study, you will be randomly placed (assigned by chance) into 1 of 2 study treatment groups. There is a:

- 1 in 2 (50%) chance of receiving the investigational drug
- 1 in 2 (50%) chance of receiving a placebo

You will continue to take your current cholesterol medication throughout the study.

Privacy, Withdrawing, Costs, and Permission

What happens to my personal information if I participate?

The study team respects and protects your privacy and will not share your information except as required by law and will store your personal information with codes that do not identify you. The Informed Consent Form (completed by you prior to participation) will provide more information about how your privacy will be maintained.

Can I withdraw from the research study early?

Your participation in the research study is entirely voluntary and you may withdraw for any reason, at any time. If you do decide to withdraw early, you will be asked to notify the study team before doing so. You will be asked to return to the study site at least once to complete a final visit and return any unused drug.

Is there a cost to participate?

No. You will receive the study treatment at no cost. You will also get all study-related medical tests at no cost.

Does my doctor have to give me permission to participate?

No, your doctor does not have to give permission for you to participate. However, either you or the study doctor, with your permission, may contact your personal doctor to discuss your participation before you begin and keep your doctor up to date about your health.

About Research Studies

What is a research study?

A research study, also known as a clinical trial, tries to answer questions about how medicines work in the people who take them. Researchers run studies to test whether an investigational medication 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 research studies. These rules are put in place to make sure research studies follow strict scientific and ethical guidelines.

Before a research study can begin, a review board or ethics committee must review the study.

Who can participate in a research study?

Only people who meet all eligibility criteria for a research study may take part. The study team at the site you select will review your medical history and current medical status against the eligibility criteria. They will determine if you are eligible to participate. You may also be asked to provide information from your medical records to help the study team determine whether you may be eligible.

What is an investigational drug?

An investigational drug is a drug that hasn't yet been approved for use in the general public. In order to be approved, the investigational drug must be tested in research studies to see if it is safe and effective for treating the target disease in certain groups of people.

The investigational drug in the CORALreef Outcomes study is being tested for people with high cholesterol to see if it may help lower cholesterol levels.

Whom can I contact if I have questions?

If you are eligible and choose to participate, the study staff will be available to answer any questions you may have.

For more answers to your questions visit: https://www.msdclinicaltrials.com/faq/

What Can You Do Next?

If you think this research study might be a good fit and you are interested in taking part, take the next step to see if you are eligible.

Discuss With Your Doctor or Research Team

Print this page with details about the study or email it to your doctor to discuss the research study during your next visit.

Get help talking with your doctor or research team

CLINICALTRIALS.GOV IDENTIFIER

NCT06008756

EU CT NUMBER

2022-502781-24

When you talk with your doctor or clinical trial team member, please have the trial identifier number available.

Taking Part in a Research Study Is an Important Decision

If you are considering joining a research study, first learn as much as you can about:

- The investigational treatment that is being studied
- What the risks and possible benefits are for participants

Talk to your doctor about the research study before you decide to join.

Read our "What to Consider" page for more questions to ask and think about

Explore Study Locations >

References:

1. What is high cholesterol? Heart UK. Accessed May 11, 2023. https://www.heartuk.org.uk/cholesterol/what-is-high-cholesterol

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