CORALreef Pediatric

Does your child have high cholesterol? If so, they may qualify for a research study

This study is testing an investigational drug to see if it may help lower cholesterol in children and adolescents with heterozygous familial hypercholesterolemia (HeFH)

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● Recruiting Print Email

About the CORALreef Pediatric Study

NATIONAL TRIAL REFERENCE NUMBER

NCT07058077

When speaking to your doctor or clinical trial representative, please have the trial reference number available.

The CORALreef Pediatric Study is testing an investigational drug to see if it may help lower cholesterol in children and adolescents with high cholesterol caused by a type of high cholesterol that runs in families called heterozygous familial hypercholesterolemia (HeFH). The investigational drug or a placebo will be taken by mouth once a day. Participants will continue to take their other cholesterol medication(s) during the trial. The investigational drug is experimental. It has not been approved to treat high cholesterol.

Researchers want to learn about:

- The safety of the investigational drug and how well it is tolerated in children
- How the body interacts with the investigational drug
- Whether the investigational drug may help to lower cholesterol levels in children over time compared to a placebo. A placebo looks like the investigational drug but has no active ingredients

How to read clinical trials
Participating in a clinical trial
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 child's doctor to discuss the research study during your next visit.

Get help talking with your doctor or research team

Does my child qualify for this study?

Your child may qualify to take part in this study if your child:

- Is 6 to less than 18 years old
- Has or might have HeFH
- Is taking medication(s) to lower high cholesterol

There are additional requirements that must be met in order to take part in this study. The study doctor will discuss all the requirements, along with the possible benefits, risks, and side effects of being in the study.

If your child qualifies and decides to participate:

- Your child will receive the investigational drug or a placebo and all study-related medical care at no cost
- Your child's cholesterol and overall health will be closely monitored by a study doctor
- You may be reimbursed for study-related travel expenses
- You may help researchers learn more about high cholesterol and the investigational drug

Participants will continue to take their current cholesterol medication during the research study.

Participation in the research study is voluntary, and your child is free to leave the study at any time. Your child's privacy will be maintained throughout the study.

Explore Study Locations >

What will happen during this study?

The study will enroll approximately 150 participants and is made up of 2 parts: Part A and Part B. A participant may be enrolled in either Part A or Part B, but not in both. After completing the study, participants may continue into an optional extension period for up to 3 years.

Key Study Facts

Part A

Study Duration

Length of study: About 3 months

Trial start and end dates

Actual study start date	**August 21, 2025**
Estimated primary completion date	**December 4, 2033**
Estimated study completion date	**January 24, 2037**

1 Screening

(up to 30 days)

At least 1 study visit for medical tests to see if your child may qualify to be in this study.

2 Treatment

(about 2 weeks)

Participants will receive the investigational drug and visit the study clinic approximately 4 to 5 times for blood tests and other assessments.

3 Follow-up

(about 8 weeks)

If your child does not enter the extension period, you will be contacted about 8 weeks after stopping the investigational drug to check on your child's health.

Part B

Study Duration

Length of study: About 9 months

Trial start and end dates

Actual study start date	**August 21, 2025**
Estimated primary completion date	**December 4, 2033**
Estimated study completion date	**January 24, 2037**

1 Screening

(up to 30 days)

2 Treatment

(about 24 weeks)

At least 1 study visit for medical tests to see if your child may qualify to be in this study.

Participants will receive the investigational drug or a placebo and visit the study clinic approximately 5 times for blood tests and other assessments.

3

Follow-up

(about 8 weeks)

If your child does not enter the extension period, you will be contacted about 8 weeks after stopping the investigational drug to check on your child's health.

Optional extension period

All participants in the extension period will take the investigational drug for up to 3 years. This period will include:

- A visit to the study site 2 months after completing Part A or Part B
- Approximately 2 visits to the study site and 2 telephone calls each year with the study doctor or a member of the study team
- A follow up health check about 8 weeks after your child stops taking the investigational drug

Will my child receive the investigational drug during the study treatment period?

- Part A: All participants will receive the investigational drug
- Part B: Participants will be randomly assigned (selected by chance) to receive the investigational drug or a placebo with a:
  - 2 in 3 (67%) chance of receiving the investigational drug- 1 in 3 (33%) chance of receiving a placebo

About HeFH

HeFH is a genetic condition that runs in families that causes very high cholesterol levels. It interferes with the liver's ability to metabolize or remove particles that carry cholesterol through the blood. This can lead to a buildup of cholesterol in arteries that narrows or blocks them, which restricts blood flow through them and increases the risk of heart disease.[1]

For healthcare professionals

The CORALreef Pediatric Study is evaluating an oral investigational PCSK9-inhibitor (PCSK9i), called MK-0616, in pediatric patients, to evaluate the safety, tolerability and pharmacokinetics of MK-0616 as well as evaluate the efficacy of MK-0616 compared with placebo.

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.

Enter ZIP code or city

Nemours/Alfred I. duPont Hospital for Children 91.14 miles

Wilmington, Delaware
United States
(302) 651-6600

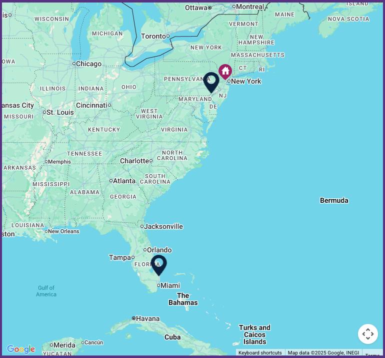
Get Directions

Excel Medical Clinical Trials 1042.34 miles

Boca Raton, Florida
United States
(561) 529-4356

Get Directions

See if you May Qualify



Frequently Asked Questions

Expand All | Collapse All

About the CORALreef Pediatric Study

Why is the CORALreef Pediatric Study being conducted?

The CORALreef Pediatric Study is evaluating the investigational drug enlicitide. Enlicitide is being tested in this study to see if it may help lower cholesterol in children and adolescents with high cholesterol caused by a type of high cholesterol that runs in families called heterozygous familial hypercholesterolemia (HeFH).

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

Before agreeing to participate, the study team will review all aspects of the research study with you and your child. If you decide your child should 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 your child.

What is a placebo, and is there a chance my child will receive one?

A placebo looks like the investigational drug but does not contain any active drug. This study is made up of two parts. There is a Part A and Part B.

- In Part A, all participants will receive the investigational drug
- In Part B, there is a 2 out of 3 (67%) chance of receiving the investigational drug, and a 1 in 3 (33%) chance of receiving a placebo

During the Optional Extension Period all participants will receive the investigational drug.

What is an extension period?

The Optional Extension Period lasts about 3 years, during which all participants receive the investigational drug. This allows researchers to collect more information about the investigational drug when taken over a longer period of time.

Privacy, Withdrawing, Costs, and Permission

What happens to my child's personal information if my child participates?

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

Can my child withdraw from the research study early?

Yes, your child's participation in the research study is entirely voluntary and your child may withdraw for any reason, at any time. If your child wants to leave early, you will be asked to notify the study team before doing so. They 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 take part?

No, the study drug and all study-related tests are provided at no cost. You may be reimbursed for study-related travel expenses.

Does my child's doctor have to give permission to participate?

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

About Research Studies

What is a research study?

A research study tries to answer questions about how medicines work in the people who take them. Researchers run studies to test whether an investigational drug 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. In the U.S., this group is called an IRB or institutional review board. An IRB is made up of doctors, scientists, and members of the community.

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 child's medical history and current medical status against the eligibility criteria. They will determine if your child is eligible to participate. You may also be asked to provide information from your child's medical records to help the study team determine whether they 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 for it 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 Pediatric Study is being tested to see how well it may work in lowering cholesterol in children and adolescents with HeFH.

Whom can I contact if I have questions?

If your child is eligible and chooses to participate, the study team will be available to answer any questions you may have.

For more answers to your questions visit: merckclinicaltrials.com/faq/

What can you do next?

If you think this research study might be a good fit for your child, take the next step to see if your child is eligible.

Discuss with your doctor or research team

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

Get help talking with your doctor or research team

Contact our Research Study Information Center

To learn more, call 1-888-577-8839.

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Taking part in a research study is an important decision

When considering a research study, it is important to learn as much as you can about:

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

Talk to your child's doctor about the clinical study before you decide to join.

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

Explore Study Locations >

Reference:

1. What Is Heterozygous Familial Hypercholesterolemia? Family Heart Foundation. Accessed August 21, 2025. https://familyheart.org/heterozygous familial hypercholesterolemia

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