Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, LLC

Drug Studied: MEDI5884

Study Title: A study to learn about the safety of MEDI5884 in participants who have stable coronary heart disease

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI5884. All of the participants helped researchers learn more about MEDI5884 to help people who have stable coronary heart disease, also called stable CHD.

MedImmune, LLC, a member of the AstraZeneca group, sponsored this study and thinks it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their important role in medical research.

If you participated in the study and have questions about the results, please speak with the doctor or staff at your study site.

What is happening with the study now?

The participants were in the study for up to about 5 months. But the entire study took about 11 months to finish.

The study started in December 2017 and ended in November 2018. It included 132 participants in the United States.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers are looking for a better way to treat patients who have heart disease. Before a drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

Stable coronary heart disease, also called stable CHD, is a condition that happens when there is a buildup of cholesterol in the heart arteries. This buildup can cause heart attack, stroke, and other medical problems. Currently, there is no cure for stable CHD.

In the body, there are 2 different types of cholesterol. There is 1 type known as “low-density lipoprotein cholesterol”, also called LDL cholesterol. LDL cholesterol is “bad cholesterol” and can clog arteries and blood vessels. The other type is “high-density lipoprotein cholesterol”, also called HDL cholesterol. This type is “good cholesterol” and helps to remove bad cholesterol from the blood.

Some available treatments to help control stable CHD work by increasing the HDL levels or decreasing the LDL levels in the blood. But these treatments may not help some people who have stable CHD, and may cause medical problems.

The study drug, MEDI5884, is being developed to help people who have stable CHD by increasing the HDL levels in the blood. In this study, the researchers wanted to learn about the safety of different doses of MEDI5884.

The main questions the researchers wanted to answer in this study were:

- Did the participants have changes in the results of their health tests and measurements during the study?
- What medical problems did the participants have during the study?

To answer the questions in this study, the researchers asked for the help of men and women who had stable CHD and were already taking heart medicine to help control their cholesterol levels. The participants in this study were 45 to 80 years old when they joined.

What kind of study was this?

This was a “double-blind” study. This means none of the participants, doctors, or other study staff knew what treatment each participant got. Some studies are done this way because knowing what treatment the participants are getting can affect the results of the study. When the study ended, the research sponsor found out which treatment the participants got so they could create a report of the study results.

The participants in the study were already taking heart medicine to help control their cholesterol levels. During the study, the participants also got MEDI5884 or a placebo as an injection through a needle under the skin. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the drug are actually caused by the drug. The MEDI5884 doses were measured in milligrams, also called mg.

A computer program was used to randomly choose the treatment each participant got. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

Before the participants got treatment, they visited their study site 1 time over the course of about 1 month. At this visit, the study doctors checked to make sure the participants could join the study. The study doctors:

- did a physical examination
- took blood and urine samples
- checked the heart health of the participants using an electrocardiogram, also called an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

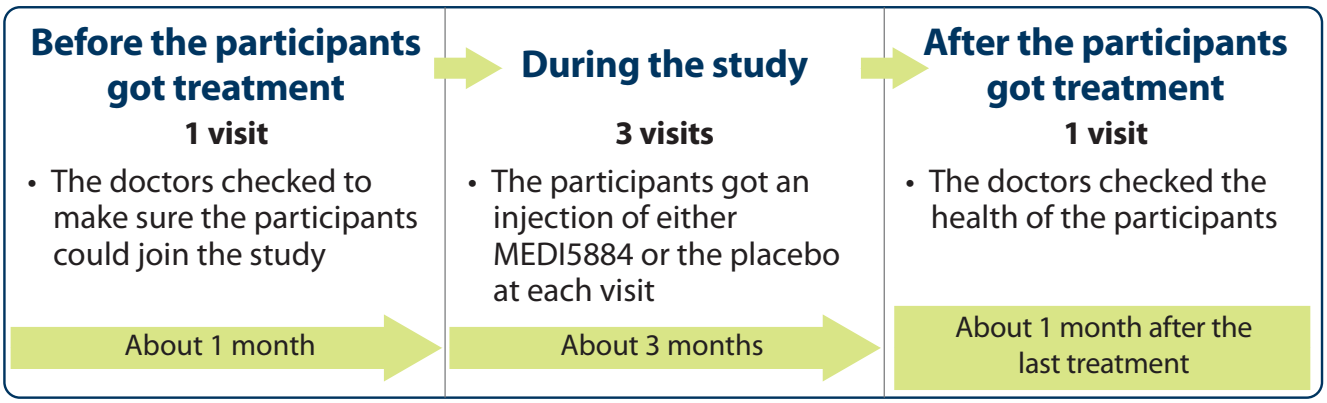
During the study, the participants visited their study site once a month for about 3 months. At each visit, the participants got either MEDI5884 or the placebo:

- 20 participants got 50 mg of MEDI5884
- 24 participants got 100 mg of MEDI5884
- 22 participants got 200 mg of MEDI5884
- 21 participants got 350 mg of MEDI5884
- 22 participants got 500 mg of MEDI5884
- 23 participants got the placebo

Throughout the study, the study doctors continued checking the participants' heart health and overall health and asked them how they were feeling.

About 1 month after getting their last treatment, the participants visited their study site 1 time. At this visit, the study doctors checked the participants' heart health and overall health and asked them how they were feeling.

The chart below shows how the study was done.



What were the results of the study?

This is a summary of the main results from this study overall. The results that each of the participants had might be different and are not in this summary. A full list of the questions the researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

Researchers look at the results of many studies to decide which treatments work best and are safest. Other studies may provide new information or different results. Always talk to a doctor before making any treatment changes.

Did the participants have changes in the results of their health tests and measurements during the study?

To answer this question, the researchers compared the results of the tests and measurements that were done before the participants got treatment to the results throughout the study.

The researchers focused on the below tests and measurements:

- physical examinations
- blood and urine samples
- heart health, by using ECGs

Overall, the researchers found that there were some changes in the participants' results during the study. But these changes were too small for the researchers to consider them to be meaningful.

The doctors also kept track of the "adverse events" that the participants had during the study. An adverse event is any sign or symptom that participants have during a study.

Doctors keep track of all of the adverse events that happen in studies, even if they do not think the adverse events might be related to the study drug. An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or the participant needs hospital care. Adverse events may or may not be caused by the study drug.

The websites listed at the end of this summary may have more information about the adverse events that happened during this study.

Serious adverse events

There were 6.8% of participants who had serious adverse events during the study. This was 9 out of 132 participants.

None of the participants died due to serious adverse events during the study.

The table below shows the serious adverse events that happened during the study.

Serious adverse events during the study

	50 mg MEDI5884 (out of 20 participants)	100 mg MEDI5884 (out of 24 participants)	200 mg MEDI5884 (out of 22 participants)	350 mg MEDI5884 (out of 21 participants)	500 mg MEDI5884 (out of 22 participants)	Placebo (out of 23 participants)
Sudden, serious chest pain near the heart	5.0% (1)	4.2% (1)	0.0% (0)	9.5% (2)	0.0% (0)	0.0% (0)
Chest pain not near the heart	0.0% (0)	0.0% (0)	0.0% (0)	4.8% (1)	0.0% (0)	4.3% (1)
Severe heart attack	5.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Heart attack	0.0% (0)	0.0% (0)	0.0% (0)	4.8% (1)	0.0% (0)	0.0% (0)
Irregular heart beat	0.0% (0)	0.0% (0)	0.0% (0)	4.8% (1)	0.0% (0)	0.0% (0)
Narrowing of blood vessels, which decreases blood flow to arms and legs	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	4.3% (1)

Adverse events

There were 57.6% of participants who had adverse events during the study. This was 76 out of 132 participants.

There were 3.0% of participants who stopped treatment due to an adverse event they had during the study. This was 4 out of 132 participants.

The table below shows how many participants had adverse events during the study.

Adverse events during the study

	50 mg MEDI5884 (out of 20 participants)	100 mg MEDI5884 (out of 24 participants)	200 mg MEDI5884 (out of 22 participants)	350 mg MEDI5884 (out of 21 participants)	500 mg MEDI5884 (out of 22 participants)	Placebo (out of 23 participants)
How many participants had adverse events during the study?	50.0% (10)	45.8% (11)	54.5% (12)	61.9% (13)	59.1% (13)	73.9% (17)
How many participants had serious adverse events during the study?	10.0% (2)	4.2% (1)	0.0% (0)	19.0% (4)	0.0% (0)	8.7% (2)
How many participants stopped treatment due to adverse events?	0.0% (0)	4.2% (1)	4.5% (1)	4.8% (1)	4.5% (1)	0.0% (0)

Most common adverse events

The most common adverse event that happened during the study was redness of the skin at the injection site.

The table below shows the adverse events that happened in at least 4 participants during the study. There were other adverse events that happened during the study, but those happened in fewer participants.

Most common adverse events during the study

	50 mg MEDI5884 (out of 20 participants)	100 mg MEDI5884 (out of 24 participants)	200 mg MEDI5884 (out of 22 participants)	350 mg MEDI5884 (out of 21 participants)	500 mg MEDI5884 (out of 22 participants)	Placebo (out of 23 participants)
Redness of the skin at injection site	0.0% (0)	4.2% (1)	13.6% (3)	19.0% (4)	0.0% (0)	8.7% (2)
Infection of the nose, throat, and airways	5.0% (1)	4.2% (1)	4.5% (1)	0.0% (0)	9.1% (2)	0.0% (0)
Sudden chest pain near the heart	5.0% (1)	4.2% (1)	0.0% (0)	9.5% (2)	0.0% (0)	0.0% (0)
Diarrhea	5.0% (1)	4.2% (1)	0.0% (0)	4.8% (1)	0.0% (0)	4.3% (1)
Nausea	0.0% (0)	4.2% (1)	0.0% (0)	4.8% (1)	4.5% (1)	4.3% (1)
Increase in apolipoprotein B, a protein found in cholesterol (increases risk of heart disease)	5.0% (1)	4.2% (1)	0.0% (0)	4.8% (1)	0.0% (0)	4.3% (1)
Common cold	5.0% (1)	0.0% (0)	0.0% (0)	4.8% (1)	4.5% (1)	4.3% (1)
Bruise on skin at injection site	0.0% (0)	0.0% (0)	0.0% (0)	4.8% (1)	4.5% (1)	8.7% (2)

What medical problems did the participants have during the study?

This section is a summary of the adverse events the participants had during the study that the study doctors thought might be related to the study drug. These adverse events are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

Adverse reactions may or may not be caused by the study drug. A lot of research is needed to know whether a drug causes an adverse reaction.

The websites listed at the end of this summary may have more information about the adverse reactions that happened during this study.

Some of the adverse reactions listed in this section are also included in the list of adverse events above.

How many participants had serious adverse reactions?

None of the participants had serious adverse reactions during the study.

How many participants had adverse reactions?

There were 14.4% of participants who had adverse reactions during the study. This was 19 out of 132 participants:

- 10.0% of the participants who got 50 mg of MEDI5884 had adverse reactions. This was 2 out of 20 participants.
- 8.3% of the participants who got 100 mg of MEDI5884 had adverse reactions. This was 2 out of 24 participants.
- 18.2% of the participants who got 200 mg of MEDI5884 had adverse reactions. This was 4 out of 22 participants.
- 23.8% of the participants who got 350 mg of MEDI5884 had adverse reactions. This was 5 out of 21 participants.
- 9.1% of the participants who got 500 mg of MEDI5884 had adverse reactions. This was 2 out of 22 participants.
- 17.4% of the participants who got the placebo had adverse reactions. This was 4 out of 23 participants.

None of the participants stopped treatment due to an adverse reaction they had during the study.

What adverse reactions did the participants have?

The most common adverse reaction that happened during the study was redness of the skin at the injection site.

The table below shows the adverse reactions that happened in at least 2 participants during the study. There were other adverse reactions that happened during the study, but those happened in fewer participants.

Most common adverse reactions during the study

	50 mg MEDI5884 (out of 20 participants)	100 mg MEDI5884 (out of 24 participants)	200 mg MEDI5884 (out of 22 participants)	350 mg MEDI5884 (out of 21 participants)	500 mg MEDI5884 (out of 22 participants)	Placebo (out of 23 participants)
Redness of the skin at injection site	0.0% (0)	4.2% (1)	13.6% (3)	19.0% (4)	0.0% (0)	8.7% (2)
Increase in apolipoprotein B, a protein found in cholesterol (increases risk of heart disease)	5.0% (1)	4.2% (1)	0.0% (0)	4.8% (1)	0.0% (0)	4.3% (1)
Increase in amount triglycerides, a type of fat, in the blood (increases risk of heart disease)	5.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)	4.5% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of MEDI5884 in people who have stable CHD.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with MEDI5884 are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If a full report of the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03351738"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D7870C00002"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 2a Randomized, Double-Blind, Placebo-controlled, Parallel-designed Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamic Effects of MEDI5884 in Subjects with Stable Coronary Heart Disease

AstraZeneca Protocol Number: D7870C00002

MedImmune, LLC, a member of the AstraZeneca Group, sponsored this study and has its headquarters at 1 Medimmune Way, Gaithersburg, MD 20878.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you!

Clinical study participants belong to a large community of people who take part in clinical research around the world. They help researchers answer important health questions and find medical treatments for patients.

CISCRP

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and informing the public about clinical research participation. CISCRP is not involved in recruiting participants for clinical studies, nor is it involved in conducting clinical studies.

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