Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, LLC

Drug Studied: MEDI5884

Study Title: A study to learn how MEDI5884 affects cholesterol levels in healthy participants, and about the safety of MEDI5884

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI5884. MedImmune, LLC, a member of the AstraZeneca group, sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results.

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 study started in January 2017 and ended in August 2018. The study included 64 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 safe it is and how it works.

There are several causes of heart disease, including the buildup of cholesterol in the arteries of the heart. There are 2 different types of cholesterol. There is 1 called “low-density lipoprotein” cholesterol, also known as LDL cholesterol. This type is considered “bad” cholesterol and can clog arteries and blood vessels.

The other type of cholesterol is called “high-density lipoprotein” cholesterol, also known as HDL cholesterol. This type is considered “good” cholesterol and helps remove bad cholesterol from the blood.

The study drug, MEDI5884, is being developed to increase HDL levels in the blood. In this study, the researchers wanted to learn if MEDI5884 affected cholesterol levels in healthy participants. They also wanted to learn about the safety of MEDI5884.

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

- Did MEDI5884 affect HDL cholesterol levels in the blood?
- Did the participants’ safety results change during the study?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done that help find out if MEDI5884 improves the health of people who have heart disease.

The researchers asked for the help of healthy men and women. The participants in this study were 22 to 54 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 got either 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 get 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. 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 participants’ heart health using an electrocardiogram, also called an ECG
- studied the participants’ vital signs
- 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 1 time and stayed at their site for up to 4 days. During this visit, the participants got an injection of either MEDI5884 or the placebo:

- 12 participants got 30 mg of MEDI5884
- 12 participants got 100 mg of MEDI5884
- 12 participants got 300 mg of MEDI5884
- 12 participants got 600 mg of MEDI5884
- 16 participants got the placebo

After the participants got treatment, they visited their study site up to 4 times over the course of about 3 months. At these visits, the study doctors checked the participants' health and asked them how they were feeling.

What were the results of the study?

This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary.

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 change.

The websites listed at the end of this summary may have a full report of the study results.

Did MEDI5884 affect HDL cholesterol levels in the blood?

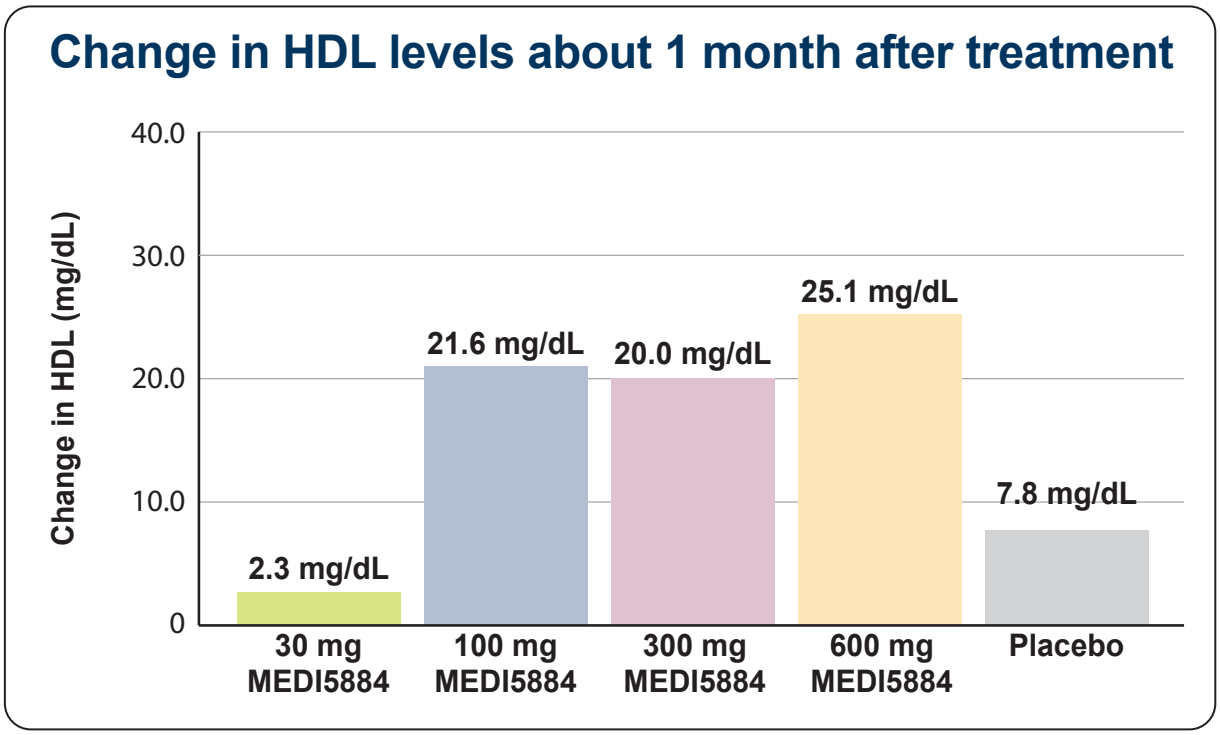
Yes. Overall, the researchers found that the participants who got MEDI5884 had an increase in their HDL cholesterol levels compared to the participants who got the placebo.

To answer this question, the researchers measured and compared the participants' HDL levels before treatment and about 1 month after treatment. The results of these measurements are listed below. The HDL levels were measured in milligrams per deciliter, also called mg/dL.

Overall, the researchers found that about 1 month after treatment:

- The participants who got 30 mg of MEDI5884 had an average increase in HDL levels of 2.3 mg/dL.
- The participants who got 100 mg of MEDI5884 had an average increase in HDL levels of 21.6 mg/dL.
- The participants who got 300 mg of MEDI5884 had an average increase in HDL levels of 20.0 mg/dL.
- The participants who got 600 mg of MEDI5884 had an average increase in HDL levels of 25.1 mg/dL.
- The participants who got the placebo had an average increase in HDL levels of 7.8 mg/dL.

The figure below shows these results.



Did the participants' safety results change during the study?

No. Overall, the researchers found that the participants' safety results did not change during the study.

To answer this question, the researchers compared the results of the tests and measurements that the doctors took throughout the study. The doctors:

- did physical examinations
- took blood and urine samples
- did ECGs
- studied the participants' vital signs

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 treatment. 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 treatments in the study.

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 1.6% of participants who had serious adverse events during the study. This was 1 out of 64 participants.

This participant was in the group who got 600 mg of MEDI5884. The participant had 2 serious adverse events:

- road traffic accident
- coma

The researchers did not think either of these serious adverse events were related to the study drug.

None of the participants died during the study.

Adverse events

There were 32.8% of participants who had adverse events during the study. This was 21 out of 64 participants.

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

Adverse events during the study					
	30 mg MEDI5884 (out of 12 participants)	**100 mg MEDI5884 (out of 12 participants)**	**300 mg MEDI5884 (out of 12 participants)**	**600 mg MEDI5884 (out of 12 participants)**	**Placebo (out of 16 participants)**
How many participants had adverse events during the study?	41.7% (5)	33.3% (4)	16.7% (2)	41.7% (5)	31.3% (5)
How many participants had serious adverse events during the study?	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)	0.0% (0)
How many participants stopped treatment due to adverse events?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

Most common adverse events

The most common adverse event during the study was headache.

The table below shows the adverse events that happened in at least 2 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

	30 mg MEDI5884 (out of 12 participants)	100 mg MEDI5884 (out of 12 participants)	300 mg MEDI5884 (out of 12 participants)	600 mg MEDI5884 (out of 12 participants)	Placebo (out of 16 participants)
Headache	8.3% (1)	8.3% (1)	0.0% (0)	0.0% (0)	18.8% (3)
Skin bruise at the injection site	0.0% (0)	8.3% (1)	0.0% (0)	16.7% (2)	0.0% (0)
Rash	16.7% (2)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Bleeding under the skin	0.0% (0)	8.3% (1)	0.0% (0)	8.3% (1)	0.0% (0)
Pain at the injection site	0.0% (0)	8.3% (1)	0.0% (0)	8.3% (1)	0.0% (0)
Redness at the injection site	0.0% (0)	8.3% (1)	0.0% (0)	8.3% (1)	0.0% (0)

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 treatment. 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 treatment. A lot of research is needed to know whether a treatment 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.

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 10.9% of participants who had adverse reactions during the study. This was 7 out of 64 participants.

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

Adverse reactions during the study

	30 mg MEDI5884 (out of 12 participants)	100 mg MEDI5884 (out of 12 participants)	300 mg MEDI5884 (out of 12 participants)	600 mg MEDI5884 (out of 12 participants)	Placebo (out of 16 participants)
How many participants had adverse reactions during the study?	8.3% (1)	25.0% (3)	0.0% (0)	16.7% (2)	6.3% (1)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions did the participants have?

The most common adverse reaction during the study was a skin bruise at the injection site.

The table below shows the adverse reactions that happened during the study.

Most common adverse reactions during the study

	30 mg MEDI5884 (out of 12 participants)	100 mg MEDI5884 (out of 12 participants)	300 mg MEDI5884 (out of 12 participants)	600 mg MEDI5884 (out of 12 participants)	Placebo (out of 16 participants)
Skin bruise at the injection site	0.0% (0)	8.3% (1)	0.0% (0)	16.7% (2)	0.0% (0)
Redness at the injection site	0.0% (0)	8.3% (1)	0.0% (0)	8.3% (1)	0.0% (0)
Pain at the injection site	0.0% (0)	8.3% (1)	0.0% (0)	8.3% (1)	0.0% (0)
Nausea	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Headache	0.0% (0)	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Itching at the injection site	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	6.3% (1)

How has this study helped patients and researchers?

This study helped researchers learn how MEDI5884 affects cholesterol levels in healthy participants, and about the safety of MEDI5884.

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 **"NCT03001297"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D7870C00001"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 1 Randomized, Blinded, Placebo-controlled Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Single-ascending Doses of MEDI5884 in Healthy Volunteers

AstraZeneca Protocol Number: D7870C00001

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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