Clinical Trial Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor:	MedImmune, LLC
Drug Studied:	MEDI6012
National Clinical Trial #:	NCT02601560
Protocol #:	D5780C00002
Study Date:	December 2015 to January 2017
Short Study Title:	A study in participants with coronary artery disease to see how MEDI6012 affects the body, how MEDI6012 acts in the body, and if MEDI6012 is safe to take

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for a drug called MEDI6012. This drug is being developed to treat coronary artery disease, or CAD. You and all of the other participants helped researchers learn how MEDI6012 affects the body, how MEDI6012 acts in the body, and if MEDI6012 is safe to take.

MedImmune, LLC, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

What has happened since my study ended?

Your study started in December 2015 and ended in January 2017. The study included 48 participants at 8 study sites in the United States. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Before a new drug can be approved, research must be done to show that it is safe and effective.

The study drug, MEDI6012, is being developed to treat coronary artery disease, or CAD. CAD is a heart disease that can cause damage to the major blood vessels of the heart. MEDI6012 was developed to reduce the buildup of cholesterol in blood vessels, including the blood vessels that supply blood to the heart. This may help decrease the chance of having a heart attack.

In this study, researchers compared 2 different forms of MEDI6012. One form was an IV treatment of MEDI6012. An IV treatment is a treatment given in a vein through a needle. The other form was an injection treatment of MEDI6012 under the skin.

Researchers also compared these 2 forms of MEDI6012 to a placebo. A placebo looks like the study drug but contains no real medicine. Researchers use a placebo so that they can compare the results of participants who take study drugs with the results of participants who take no medicine at all.

Researchers wanted to know:

- Did MEDI6012 increase the amount of good cholesterol in participants' blood more than the placebo?
- How did MEDI6012 act in the body?
- What medical problems did participants have after getting MEDI6012?

What kind of study was this?

Your study was a "double-blind" study. This means that none of the participants, researchers, or staff knew what treatment each participant got. Some studies are done this way because knowing what treatment each participant is getting can affect the results of the study. This way, the results are looked at fairly.

You and the other participants got MEDI6012 or a placebo. Which treatment participants got was decided by chance, like rolling dice. For every 3 participants who got MEDI6012, 1 participant got a placebo.

Your study included 48 men and women with CAD who were 48 to 74 years old.

What happened during the study?

You and other participants were in the study for up to about 2 months or longer if needed.

To see if you could join the study, study doctors did a physical examination by checking your height, weight, and temperature. Study doctors took blood and urine samples and checked your heart health using an electrocardiogram, or ECG. Study doctors also asked about your medical history, how you were feeling, and what medicines you were taking.

If you are female, you had a blood test to make sure you were not pregnant.

All of the participants visited their study site at least 3 or 4 times.

The first visit was a screening visit to see if the participants could join the study.

The second visit was the treatment visit, in which participants got MEDI6012 or a placebo. During the second visit, researchers checked to see if the immune systems of participants made antibodies against MEDI6012 in the blood.

Antibodies are normally made by the immune system of the body to fight off infection. If antibodies against MEDI6012 form, the drug may not work as well, or it may cause an allergic reaction to the drug. One or both of these reactions could happen, or neither of these reactions could happen.

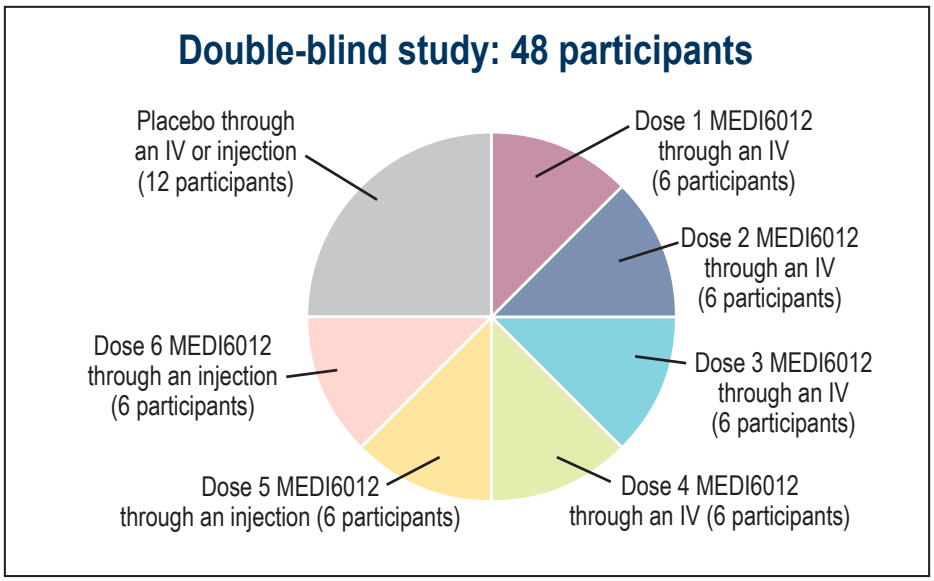
At the end of the study, all participants returned to their study site for a fifth visit. This was a follow-up visit about 1 month after the treatment visit. Study doctors again checked to see if the immune systems of participants made antibodies against MEDI6012 in the blood.

If the immune systems of participants made antibodies against MEDI6012, then these participants returned to the study site about 1 month after the follow-up visit for another visit. This visit was so that study doctors could check if these antibodies had affected the health of these participants.

There were 7 treatments in this study, but all of the participants got only 1 of these 7 treatments. They got an IV treatment of MEDI6012, an injection treatment of MEDI6012 under the skin, or a placebo. An IV treatment is a treatment given in a vein through a needle. The 7 treatments in this study are listed on the next page.

Six of the 8 treatments had different doses of MEDI6012, and 2 treatments had a placebo.

The figure below shows how the study was done.



During the study, study doctors did another physical examination and checked each participants' height, weight, and temperature. The study doctors also tested participants' blood and urine to make sure that participants were still healthy, and asked participants how they were feeling. Study doctors also checked each participant's heart health using an ECG.

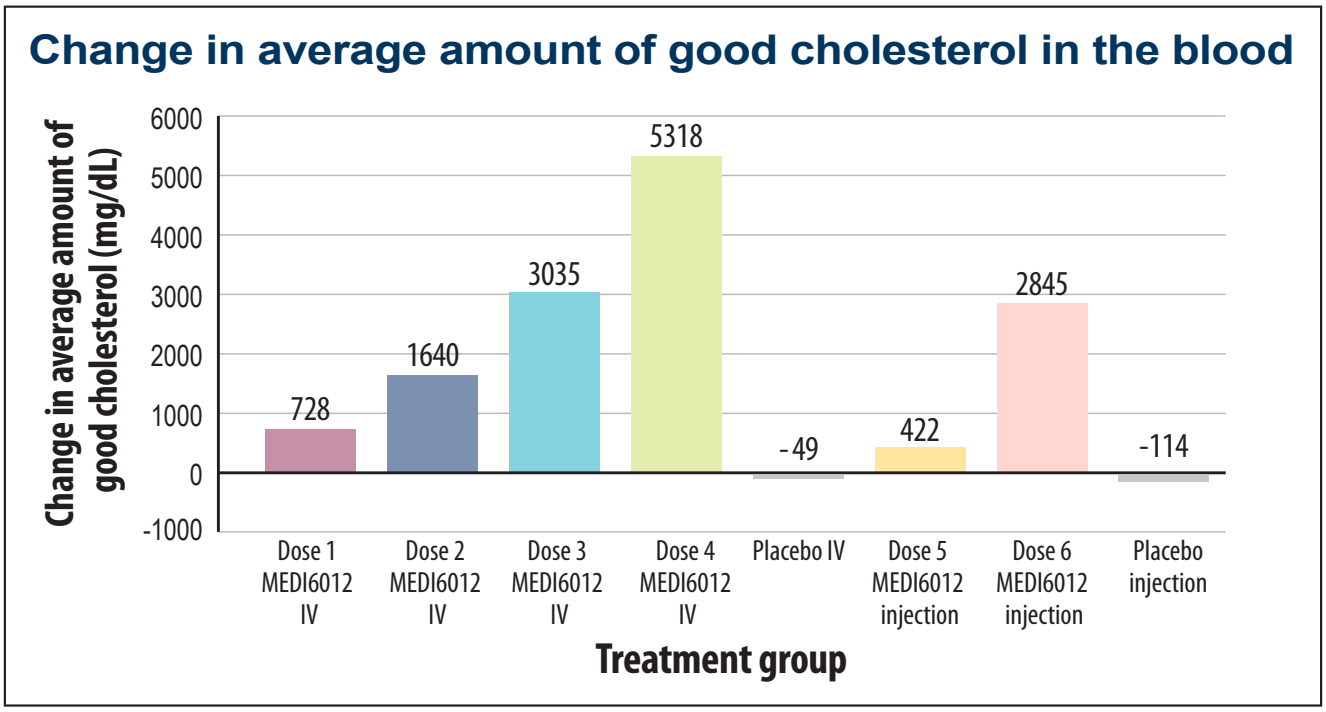
What were the study results?

Below is a summary of the results of some of the questions the researchers asked during this study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with MEDI6012 are currently planned.

Did MEDI6012 increase the amount of good cholesterol in participants' blood more than the placebo?

Researchers wanted to know how the study drug affected the body. They wanted to see if MEDI6012 treatment increased the amount of good cholesterol in the blood of participants. Researchers found that the amount of good cholesterol in the blood increased in the first 96 hours after treatment with MEDI6012. Participants who got the placebo didn't have these increases.

The chart below shows the total change in the amount of good cholesterol in the blood over the first 96 hours after treatment with MEDI6012 or placebo. The amount of good cholesterol in the blood was measured in milligrams per deciliter of blood, or mg/dL. This is a widely accepted scientific unit of measurement.



Researchers found that the amount of good cholesterol in the blood increased the most for the participants who got the Dose 4 IV of MEDI6012.

Researchers also found that:

- By Days 8 and 15 after getting treatment, the amount of good cholesterol in the blood returned to the levels participants had before getting MEDI6012.
- Participants who got higher doses of MEDI6012 had higher levels of good cholesterol in their blood.

How did MEDI6012 act in the body?

Researchers wanted to know how the study drug acted in the body. So they measured:

- The average amount of MEDI6012 in the blood
- The highest amount of MEDI6012 in the blood
- How long it took for MEDI6012 to reach its highest amount in the blood

Generally, the amount of MEDI6012 was too small to be measured in participants who got Dose 5 of MEDI6012 through an injection. For all other treatment groups, researchers found that:

- The average amounts of MEDI6012 in the blood were larger in participants who got the higher doses of the study drug.
- The participants who got the higher doses of MEDI6012 had the highest amounts of MEDI6012 in the blood.
- It took longer for MEDI6012 to reach its highest amount in the blood for participants who got the higher doses of the study drug.

What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem. Researchers keep track of all medical problems that participants have during the study. These medical problems are called "adverse events". They may or may not be caused by the study drug.

How many participants had medical problems during the study?

A similar number of participants who got the MEDI6012 IV treatment and the MEDI6012 injection treatment had adverse events.

The table below shows how many participants in the study had medical problems. No participants stopped taking the drug because of a medical problem.

How many participants developed medical problems?

Dose 1 of MEDI6012 IV (Out of 6 participants)	Dose 2 of MEDI6012 IV (Out of 6 participants)	Dose 3 of MEDI6012 IV (Out of 6 participants)	Dose 4 of MEDI6012 IV (Out of 6 participants)	Placebo - IV (Out of 8 participants)	Dose 5 of MEDI6012 Injection (Out of 6 participants)	Dose 6 of MEDI6012 Injection (Out of 6 participants)	Placebo - Injection (Out of 4 participants)	All Participants (Out of 48 participants)
2 (33.3%)	5 (83.3%)	2 (33.3%)	4 (66.7%)	3 (37.5%)	3 (50.0%)	4 (66.7%)	2 (50.0%)	25 (52.1%)

How many participants had serious medical problems?

A medical problem is considered serious when it is life-threatening, causes lasting problems, or needs hospital care. In this study, no participants developed serious medical problems, and no participants died.

What were the most common non-serious medical problems in the study?

The most commonly reported adverse events in participants were headache (8.3%), nausea (6.3%), and skin reaction at the injection site (6.3%).

The table below shows the most common medical problems that happened during the study.

Medical problems that were not serious

	Dose 1 of MEDI6012 IV (Out of 6 participants)	Dose 2 of MEDI6012 IV (Out of 6 participants)	Dose 3 of MEDI6012 IV (Out of 6 participants)	Dose 4 of MEDI6012 IV (Out of 6 participants)	Placebo - IV (Out of 8 participants)	Dose 5 of MEDI6012 Injection (Out of 6 participants)	Dose 6 of MEDI6012 Injection (Out of 6 participants)	Placebo - Injection (Out of 4 participants)	All Participants (Out of 48 participants)
Headache	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	2 (33.3%)	0 (0.0%)	4 (8.3%)
Nausea	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (50.0%)	3 (6.3%)
Skin reaction at the injection site	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	3 (6.3%)
Constipation	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	2 (4.2%)
Irritation at the site of a medical device	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.2%)
Redness where the injection was given	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)	0 (0.0%)	2 (4.2%)

Where can I learn more about this clinical study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/NCT02601560.

Official study title: A Phase 2a Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Single Ascending Doses of MEDI6012 in Subjects with Stable Coronary Artery Disease

MedImmune, LLC, the sponsor of this study, is a member of the AstraZeneca Group of companies.

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

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.