AstraZeneca

Clinical Study Results

Research Sponsor: MedImmune LLC

Drug Studied: MEDI6012

Study Purpose: This study was done to learn how well MEDI6012 worked in participants who had a type of heart attack called a STEMI

Protocol Number: D5780C00007

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI6012.

All of the participants helped the researchers learn more about MEDI6012 to help people who had a sudden heart attack caused by a blockage in the arteries that supply blood to the heart. This type of heart attack is called an "ST elevation myocardial infarction", also called a STEMI.

MedImmune, LLC, sponsored this study and believes it is important to share the results of the study with you and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you. We hope it helps you understand and feel proud of your important role in medical research.

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

Overview of this study

Why was the research needed?

Researchers are looking for a better way to treat STEMIs. All of the participants in this study had a STEMI. In this summary we will use the term "heart attack" instead of "STEMI". Before a drug can be approved for people to receive, researchers do clinical studies to find out how it works and how safe it is.

What treatments did the participants receive?

The participants in this study received MEDI6012 or a placebo. A placebo looks like a drug but does not have any medicine in it.

What were the results of this study?

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

- **Did MEDI6012 help reduce heart muscle damage after a heart attack?**

  Overall, the researchers found that there were some small reductions in the participants' heart muscle damage. But, the difference between the participants who received MEDI6012 and those who received the placebo was too small for the researchers to know if MEDI6012 reduced heart muscle damage.

- **What medical problems did the participants have during this study?**

  There were 1.6% of participants who had medical problems that the study doctors thought might be related to the study drug during the study. This was 9 out of 575 participants. The most common medical problem was abnormal electrical activity of the heart that affects its rhythm.

More details about the results of this study are included later in this summary.

Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on those websites.

Who took part in this study?

The researchers asked for the help of men and women who recently had a sudden heart attack caused by a blockage in the arteries that supply blood to the heart. This type of heart attack is called an ST elevation myocardial infarction, also called a "STEMI". The participants in this study were 34 to 80 years old when they joined.

All of the participants:

- were planned to receive a treatment called primary percutaneous coronary intervention, also called "pPCI," which helps open blocked arteries.
- had heart attack symptoms for less than 6 hours.

People whose heart could not pump enough blood to meet the body's needs, had received CPR, or had been given medicine to break down blood clots before or after they arrived at the hospital could not join this study. People who had a previous heart attack or a type of surgery called a coronary artery bypass graft that helps blood get past clogged arteries also could not take part in this study.

The study included 593 participants in Brazil, the Czech Republic, Hungary, Israel, the Netherlands, Poland, Russia, Slovakia, Spain, and the United Kingdom.

Why was the research needed?

Researchers are looking for a better way to treat heart attacks. Before a drug can be approved for people to receive, researchers do clinical studies to find out how it works and how safe it is.

In this study, the researchers wanted to find out if MEDI6012 worked in participants who were having a heart attack. They also wanted to find out if the participants had any medical problems during the study.

STEMI heart attacks are usually caused by a complete blockage in the arteries that supply blood to the heart. This causes serious damage to the heart tissue. The damaged tissue is called an "infarct".

The main treatment for a heart attack is called "pPCI", which is a procedure that aims to quickly remove the blockage and to keep the arteries open. The study drug, MEDI6012, was designed to be given to patients before pPCI. Researchers think that MEDI6012 may help protect the heart tissues from becoming damaged after a heart attack. It also acts to increase the amount of good cholesterol and a protein called "apoA1" in the blood, which might help to reduce the amount of cholesterol plaque in the arteries.

In this study, the researchers wanted to find out if MEDI6012 reduces the size of infarcts in people who have recently had a heart attack.

What was the purpose of this study?

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

- Did MEDI6012 help to reduce heart muscle damage after a heart attack?
- 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 to find out if MEDI6012 helps improve the health of people after a heart attack.

What treatments did the participants receive?

In this study, the participants received either MEDI6012 or the placebo. 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 receive the drug are actually caused by the drug.

None of the participants or the sponsor knew what treatment each participant was receiving. Some studies are done this way because knowing what treatment the participants are receiving can affect the results of the study. When the study ended, the research sponsor found out which treatment the participants received so they could create a report of the study results. The study staff knew which treatment each participant received, but they tried to make sure that the study doctors did not find out this information so that it did not affect the study results.

A computer program was used to randomly choose the treatment each participant received. 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.

The participants received MEDI6012 or the placebo through a needle into a vein, also known as an IV infusion. The dose of MEDI6012 was measured in milligrams, also known as "mg".

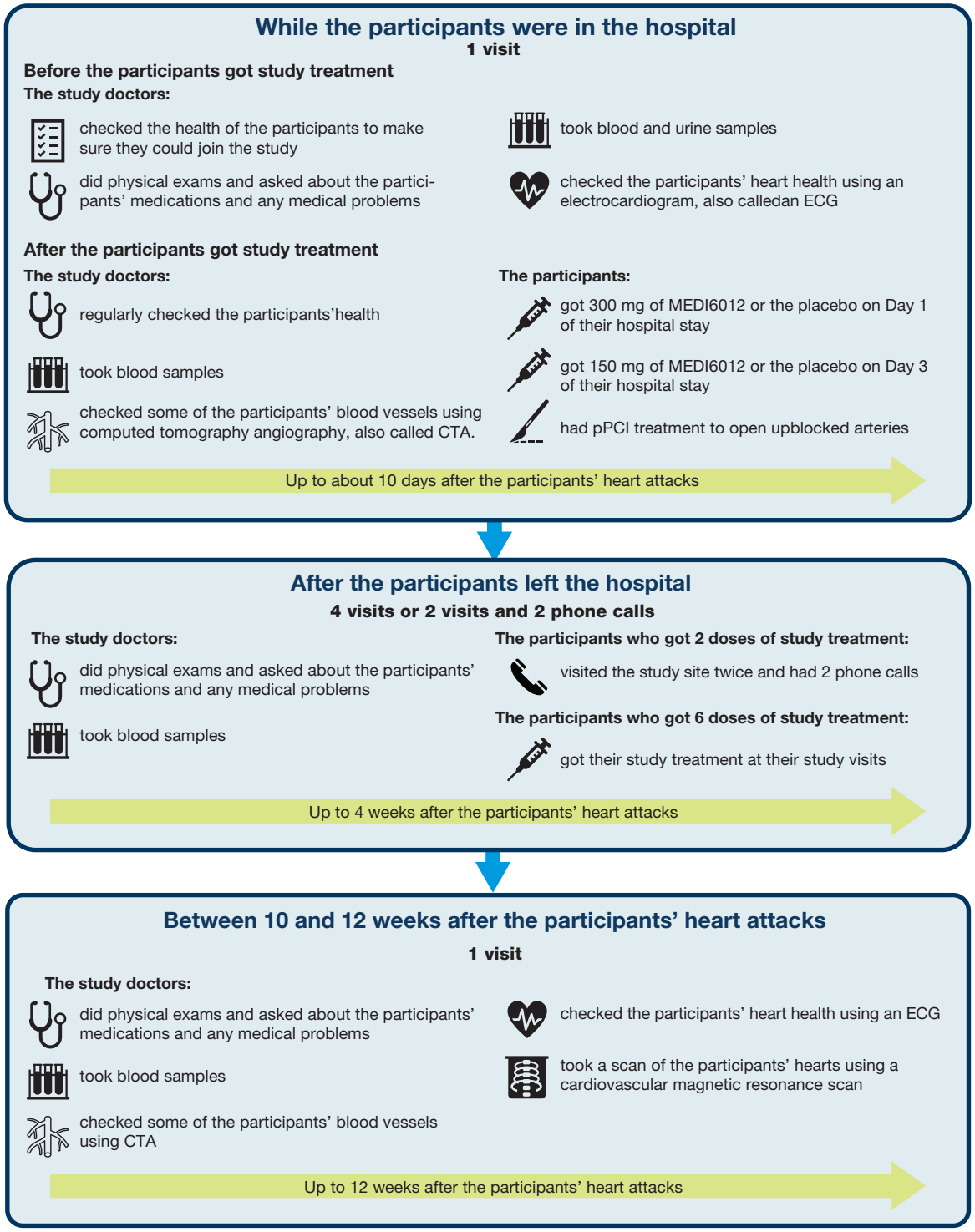
There were 18 participants who joined the study but did not receive any treatment. The chart below only shows the planned treatments for the participants who received at least 1 dose of MEDI6012 or the placebo.

	Group 1	Group 2	Group 3	
	179 participants	195 participants	90 participants	111 participants
	MEDI6012 as an IV infusion		The placebo as an IV infusion	
	• 300 mg on the first day in the hospital • 150 mg 2 days later	• 300 mg on the first day in the hospital • 150 mg 2 days later • 100 mg once a week for 4 weeks	• Placebo on the first day in the hospital • Placebo 2 days later	• Placebo on the first day in the hospital • Placebo 2 days later • Placebo once a week for 4 weeks

What happened during this study?

The participants were in the study for up to about 3 months. But the entire study took about 2.5 years to finish. The study started in June 2018 and ended in January 2021.

The chart below shows what happened during the study.



What were the results of this 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. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When 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.

For this part of the study, the researchers only used data from the participants who received at least 2 doses of their study drug and whose arteries were completely blocked or almost completely blocked. The results from Group 3 and 4, who both received the placebo, were analyzed as a single group.

Did MEDI6012 help to reduce heart muscle damage after a heart attack?

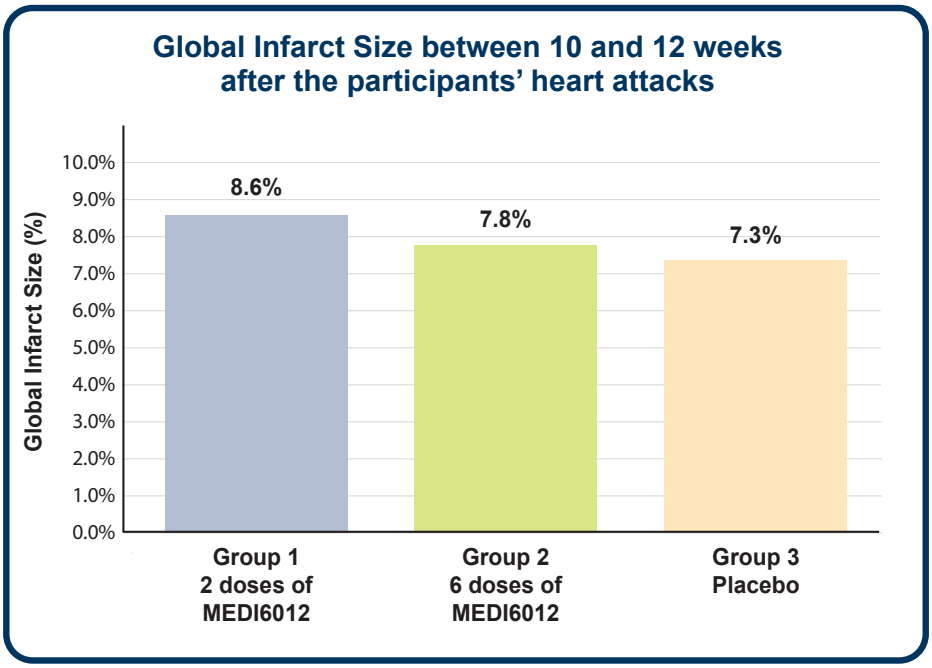
Overall, the researchers found that there were some small reductions in the amount of heart muscle damage. But, the difference between the participants who received MEDI6012 and those who received the placebo was too small for the researchers to know if MEDI6012 reduced heart muscle damage.

To answer this question, the researchers took a scan of the participants' hearts using a cardiovascular magnetic resonance scan. They took this scan between 10 and 12 weeks after each participant's heart attack. From the scan, they determined how much muscle damage there was and the size of a part of the heart known as the "left ventricle". Then they calculated how big the amount of heart muscle damage was compared to the left ventricle as a percentage. This percentage is called the "Global Infarct Size".

Overall, the researchers found that the Global Infarct Size was:

- 8.6% in **Group 1, who got 2 doses of MEDI6012**
- 7.8% in **Group 2, who got 6 doses of MEDI6012**
- 7.3% in **Group 3, who got the placebo**

These results are shown in the graph below.



What medical problems happened during this study?

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

These 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for MEDI6012.

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

Did any adverse reactions happen during this study?

There were 1.6% of participants who had medical problems that the study doctors thought might be related to the study drug during the study. This was 9 out of 575 participants.

	Group 1 2 doses of MEDI6012 (out of 179 participants)	Group 2 6 doses of MEDI6012 (out of 195 participants)	Group 3 Placebo (out of 201 participants)
How many participants had adverse reactions?	1.1% (2)	3.6% (7)	0.0% (0)
How many participants had serious adverse reactions?	0.0% (0)	0.5% (1)	0.0% (0)
How many participants stopped receiving study treatment due to adverse reactions?	0.0% (0)	1.5% (3)	0.0% (0)

What serious adverse reactions happened during this study?

The only serious adverse reaction was skin pain and rash. This serious adverse reaction happened in 1 out of 195 participants in Group 2. This was 0.5% of participants in Group 2.

None of the participants died because of serious adverse reactions.

What adverse reactions happened during this study?

The most common adverse reaction was abnormal electrical activity of the heart that affects its rhythm.

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

Adverse reactions

Adverse reaction	Group 1 (out of 179 participants)	Group 2 (out of 195 participants)	Group 3 (out of 201 participants)
Abnormal electrical activity of the heart that affects its rhythm	1.1% (2)	0.0% (0)	0.0% (0)
Diarrhea	0.0% (0)	0.5% (1)	0.0% (0)
Lip swelling	0.0% (0)	0.5% (1)	0.0% (0)
Nausea	0.0% (0)	0.5% (1)	0.0% (0)
Vomiting	0.0% (0)	0.5% (1)	0.0% (0)
Reaction to study treatment	0.0% (0)	0.5% (1)	0.0% (0)
Headache	0.0% (0)	0.5% (1)	0.0% (0)
Skin inflammation caused by an allergy	0.0% (0)	0.5% (1)	0.0% (0)
Skin pain and rash	0.0% (0)	0.5% (1)	0.0% (0)
An itchy rash	0.0% (0)	0.5% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about how well MEDI6012 worked to reduce the size of infarcts after a heart attack.

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 MEDI6012 are not planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. When 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 **"NCT03578809"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home and Search"**, then type **"2017-004521-32"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D5780C00007"** into the search box, and click **"Find a Study"**.

Full Study Title: A Randomized, Placebo-controlled, Phase 2b Study to Evaluate the Safety and Efficacy of MEDI6012 in Acute ST Elevation Myocardial Infarction (REAL-TIMI 63B)

MedImmune LLC Protocol Number: D5780C00007

National Clinical Trials Number: NCT03578809

EudraCT Number: 2017-004521-32

MedImmune LLC sponsored this study and has its headquarters in Gaithersburg, MD, USA.

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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