AstraZeneca

Clinical Study Results

Research Sponsor: MedImmune LLC

Treatment Studied: MEDI6570

Study Purpose: This study was done to learn about the safety of MEDI6570 in participants with type 2 diabetes

Protocol Number: D4920C00001

Thank you!

Thank you for taking part in the clinical study for the study treatment MEDI6570.

MedImmune LLC sponsored this study and believes it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you.

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

Who took part in this study?

The researchers asked for the help of men and women with type 2 diabetes, also called T2DM. The participants in this study were 36 to 65 years old when they joined.

The study included 88 participants in the United States.

Why was the research needed?

Researchers are looking for a better way to treat people who are at risk of having heart problems due to heart and blood vessel disease. This is also known as cardiovascular disease. This is usually caused by inflammation and high levels of fat in the blood.

The study treatment, MEDI6570, was designed to reduce inflammation. This is the first time MEDI6570 has been studied in people, so the researchers wanted to find out about the safety of MEDI6570 in healthy participants. But, healthy people usually do not have high enough levels of inflammation to be studied. So, the researchers asked for participants with T2DM who were otherwise healthy to join the study.

What was the purpose of this study?

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

- What signs and symptoms did the participants have?
- 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 MEDI6570 helps improve the health of people with cardiovascular disease.

What treatments did the participants take?

In this study, the participants received 1 of several different possible doses of MEDI6570, or a placebo. These were given through a needle under the skin, also known as an injection. A placebo looks like a treatment 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 treatment are actually caused by the treatment.

This was a "double-blind" study. This means none of the participants, study doctors, or other study staff knew whether the participants were receiving MEDI6570 or the placebo. Some studies are done this way because knowing what treatment the participants are receiving can affect the results of the study.

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 study happened in 2 parts. In Part A, the participants received a single dose injection of study treatment. The single dose could have been given through several injections. In Part A:

- 36 participants received 1 of 5 different doses of MEDI6570
- 12 participants received the placebo

The early results of Part A were used to decide which doses of MEDI6570 should be used in Part B. In Part B, the participants received a total of 3 doses, which were given once a month for a total of 3 months. Each dose could have been given through several injections. In Part B:

- 30 participants received 1 of 3 different doses of MEDI6570
- 10 participants received the placebo

The chart below shows the treatments the researchers planned to study.

<table>
<tr><th></th><th colspan="2">Part A</th><th colspan="2">Part B</th></tr>
<tr><td></td><td>MEDI6570</td><td>Placebo</td><td>MEDI6570</td><td>Placebo</td></tr>
<tr><td>  </td><td>36 participants</td><td>12 participants</td><td>30 participants</td><td>10 participants</td></tr>
<tr><td>  </td><td colspan="4">A needle under the skin, also known as an injection</td></tr>
<tr><td>  </td><td colspan="2">A single dose</td><td colspan="2">A total of 3 doses, given once a month for a total of 3 months</td></tr>
</table>

What happened during this study?

The study started in September 2018 and ended in July 2020.

Part A

Before the participants in Part A received study treatment, they visited their study site 1 time. This part of the study lasted for up to 4 weeks. At this visit, the study doctors made sure the participants could join the study. They also:

- did a physical exam and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also known as an ECG

The study doctors also did these tests and measurements throughout the study.

While the participants in Part A were receiving study treatment, they visited their study site 1 time. Most of the participants stayed overnight at their study site for 3 nights, but some could go home for the nights. During this visit, they received their dose of study treatment.

After the participants in Part A received study treatment, they visited their study site or had a telephone call from the study staff up to 11 times over 3 to 6 months. The exact number of visits or calls depended on the dose of MEDI6570 each participant received. At these visits and calls, the study doctors checked the health of the participants.

Part B

Before the participants in Part B received study treatment, they visited their study site 2 times. At the first visit, the study doctors made sure the participants could join the study. They also:

- did a physical exam and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- checked the participants' heart health using an ECG

The study doctors also did these tests and measurements throughout the study.

At the second visit, the study doctors also checked the participants' heart and blood vessel health using a scan called a computed tomography angiography, also known as a CTA.

While the participants in Part B were receiving study treatment, they visited their study site 1 time and stayed overnight at their study site for 3 days. Then, they visited their study site 4 more times over 8 weeks. At some of these visits, they received their doses of study treatment.

After the participants in Part B received study treatment, they visited their study site or had a telephone call from the study staff up to 6 times over 3 to 6 months. The exact number of visits or calls depended on the dose of MEDI6570 each participant received. At these visits and calls, the study doctors checked the health of the participants. At 1 of these visits, the study doctors also did another CTA scan.

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.

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.

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

Because each of the different dose groups of MEDI6570 had a very small number of participants, the results for each group have been combined into Part A and Part B. Showing the information this way helps protect the participants' identities. Overall, the researchers found that the results for each dose of MEDI6570 were similar.

What signs and symptoms did the participants have during this study?

To answer this question, the study doctors did tests and measurements before and after the participants received study treatment. The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also did ECGs to check the participants' heart health. Overall, the study doctors did not think there were any results in these tests and measurements that were important.

The study doctors also kept track of the "adverse events" that the participants had.

An adverse event is any sign or symptom that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment.

Later in this document, there will be a summary of the adverse events that the study doctors thought might be related to the study treatments. This section is a summary of all the adverse events, whether they might be related to the study treatments or not. 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. A lot of research is needed to know whether a treatment causes an adverse event.

	Part A		Part B	
	MEDI6570 (out of 36 participants)	**Placebo (out of 12 participants)**	**MEDI6570 (out of 30 participants)**	**Placebo (out of 10 participants)**
How many participants had adverse events?	61.1% (22)	50.0% (6)	73.3% (22)	70.0% (7)
How many participants had serious adverse events?	5.6% (2)	0.0% (0)	6.7% (2)	10.0% (1)

None of the participants stopped taking study treatment due to adverse events.

The serious adverse events in Part A were:

- allergic reaction to a different drug, not the study treatment
- infection in the knee bone

The serious adverse events in Part B were:

- kidney stones
- inflammation of the intestines caused by a lack of blood supply
- wound and blood infection after surgery

The most common adverse events in Part A were:

- infections in the upper airways, such as colds, sore throats, and sinus infections
- back pain
- bruising
- muscle strain
- fever
- painful and stiff joints

The most common adverse events in Part B were:

- infections in the upper airways, such as colds, sore throats, and sinus infections
- diarrhea
- injection site reaction
- lung infection
- constipation
- injection site redness
- pain in the arms and legs

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 treatments. These medical problems are also 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 treatments. A lot of research is needed to know whether a treatment causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for MEDI6570.

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.

Because each of the different dose groups of MEDI6570 had a very small number of participants, the results for each group have been combined into Part A and Part B. Showing the information this way helps protect the participants' identities. Overall, the researchers found that the results for each dose of MEDI6570 were similar.

Did any adverse reactions happen during this study?

There were 9.1% of participants who had adverse reactions during the study. This was 8 out of 88 participants.

- 5.6% of the participants who received MEDI6570 in Part A had adverse reactions. This was 2 out of 36 participants.
- 16.7% of the participants who received the placebo in Part A had adverse reactions. This was 2 out of 12 participants.
- 6.7% of the participants who received MEDI6570 in Part B had adverse reactions. This was 2 out of 30 participants.
- 20.0% of the participants who received the placebo in Part B had adverse reactions. This was 2 out of 10 participants.

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

None of the participants stopped taking study treatment due to adverse reactions.

What serious adverse reactions happened during this study?

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

What adverse reactions happened during this study?

The most common adverse reaction was an injection site reaction.

The table below shows the adverse reactions that happened during the study. Some participants had more than 1 adverse reaction.

Adverse reactions

	Part A		Part B	
	MEDI6570 (out of 36 participants)	Placebo (out of 12 participants)	MEDI6570 (out of 30 participants)	Placebo (out of 10 participants)
Injection site reaction	2.8% (1)	0.0% (0)	3.3% (1)	10.0% (1)
Nausea	2.8% (1)	8.3% (1)	0.0% (0)	0.0% (0)
Diarrhea	0.0% (0)	8.3% (1)	0.0% (0)	10.0% (1)
Loss of the outer layer of skin at the injection site	0.0% (0)	8.3% (1)	0.0% (0)	0.0% (0)
Headache	0.0% (0)	8.3% (1)	0.0% (0)	0.0% (0)
Low appetite	0.0% (0)	0.0% (0)	3.3% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of MEDI6570 in participants with T2DM.

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 1 study. Other studies may provide new information or different results.

Further clinical studies with MEDI6570 are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

- www.clinicaltrials.gov Once you are on the website, type **"NCT03654313"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D4920C00001"** into the search box, and click "**Find a Study".**

Full Study Title: A Phase 1 Randomized, Blinded, Placebo-controlled Study to Evaluate the Safety and Pharmacokinetics of Single and Multiple Ascending Doses of MEDI6570 in Subjects With Type 2 Diabetes Mellitus

MedImmune LLC Protocol Number: D4920C00001

National Clinical Trials Number: NCT03654313

MedImmune LLC sponsored this study and has its headquarters at 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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