Clinical Study Results

Research Sponsor: MedImmune, LLC

Drug Studied: MEDI0382

Study Title: A study to learn how MEDI0382 affects blood sugar and weight in people who have type 2 diabetes, and if MEDI0382 is safe to take

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI0382. All the participants helped researchers learn more about using MEDI0382 to help people who have type 2 diabetes and who are overweight or have obesity.

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 study started in August 2018 and ended in January 2019. It included 61 participants in Japan.

The participants were in the study for up to about 2.5 months. But, the entire study took about 5 months to finish.

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 people who have type 2 diabetes and who are overweight or have obesity. 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.

In this study, the researchers wanted to learn how MEDI0382 affects blood sugar and weight in people who have type 2 diabetes and who are overweight or have obesity. They also wanted to learn more about the safety of MEDI0382.

In people who have type 2 diabetes, the body does not use insulin as well as it should. Insulin is a hormone made by the pancreas that controls the levels of sugar in the blood. If a person's blood sugar levels become too high, he or she can have medical problems. High blood sugar can also lead to increased food cravings and decreased energy levels, which can cause weight gain.

There are treatments for type 2 diabetes that help control blood sugar, but these treatments may not help control weight gain in some people. The study drug, MEDI0382, is being developed to help people who have type 2 diabetes control their blood sugar levels. It was designed to help the body make insulin, control food cravings, and increase energy levels.

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

- Did MEDI0382 affect the participants' blood sugar levels?
- Did MEDI0382 affect the participants' weight?
- Did the participants' safety results change 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 type 2 diabetes and were overweight or had obesity. The participants in this study were 32 to 77 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.

In this study, the participants got either MEDI0382 or a 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 get the drug are actually caused by the drug.

In this study, both MEDI0382 and the placebo were given through a needle under the skin, which is called an injection. The MEDI0382 doses were measured in micrograms, also called µg.

This was also a “dose-escalation” study. This means that the participants who got MEDI0382 started on a low dose. After the researchers carefully studied the results, they increased the MEDI0382 doses for these participants.

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 study treatment, they visited their study site 2 times over the course of 2 weeks. At these visits, 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
- checked the participants’ blood sugar levels
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

During the study, the participants were in 1 of 4 treatment groups. They visited their study site 10 times over the course of about 7 weeks. The participants got their first 5 injections at the study site. Then, they could inject themselves at home. The chart below shows the different treatment groups.

Group Number	5 days	7 days	7 days	29 days
Group 1 (lowest dose) 15 participants	50 µg of MEDI0382 each day	100 µg of MEDI0382 each day	100 µg of MEDI0382 each day	100 µg of MEDI0382 each day
Group 2 (middle dose) 15 participants	50 µg of MEDI0382 each day	100 µg of MEDI0382 each day	200 µg of MEDI0382 each day	200 µg of MEDI0382 each day
Group 3 (highest dose) 15 participants	50 µg of MEDI0382 each day	100 µg of MEDI0382 each day	200 µg of MEDI0382 each day	300 µg of MEDI0382 each day
Group 4 (placebo) 16 participants	Placebo each day	Placebo each day	Placebo each day	Placebo each day

About 2 weeks after their last treatment, the participants visited their study site 1 time. At this visit, the study doctors checked the participants' health and blood sugar levels, 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. 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 MEDI0382 affect the participants' blood sugar levels?

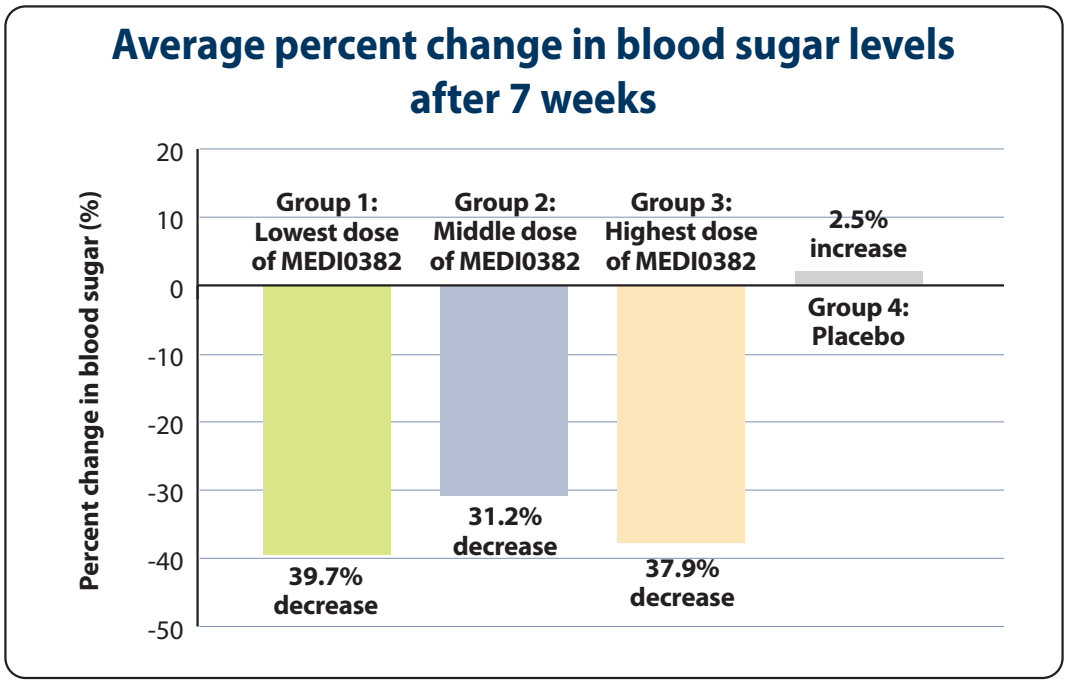
Yes. Overall, the researchers found that the participants who got MEDI0382 had a decrease in their blood sugar levels. The researchers also found that the participants who got the placebo had an increase in their blood sugar levels.

To answer this question, the researchers measured the participants' blood sugar levels before they got treatment, and at the end of the study. Then, the researchers compared the percent change in these measurements.

The researchers found that after 7 weeks of treatment, the participants in:

- Group 1, who got the lowest dose, of MEDI0382 had an average decrease in their blood sugar levels of 39.7%.
- Group 2, who got the middle dose of MEDI0382, had an average decrease in their blood sugar levels of 31.2%.
- Group 3, who got the highest dose of MEDI0382, had an average decrease in their blood sugar levels of 37.9%.
- Group 4, who got the placebo, had an average increase in their blood sugar levels of 2.5%.

The figure below shows these results.



Did MEDI0382 affect the participants' weight?

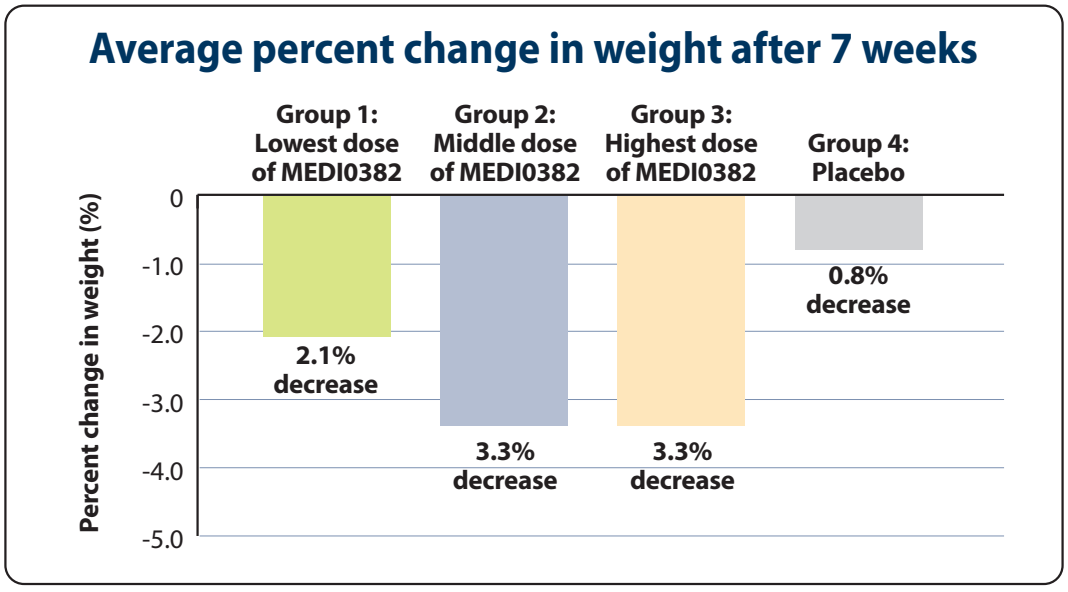
Yes. Overall, the researchers found that the participants in all 4 treatment groups lost weight after getting treatment. They also found that the participants who got MEDI0382 lost more weight compared to the participants who got the placebo.

To answer this question, the researchers measured the participants' weight before they got treatment, and at the end of the study. Then, the researchers compared the percent change in these measurements.

The researchers found that after 7 weeks of treatment, the participants in:

- Group 1, who got the lowest dose of MEDI0382, had an average decrease in their weight of 2.1%.
- Group 2, who got the middle dose of MEDI0382, had an average decrease in their weight of 3.3%.
- Group 3, who got the highest dose of MEDI0382, had an average decrease in their weight of 3.3%.
- Group 4, who got the placebo, had an average decrease in their weight of 0.8%.

The figure below shows these results.



Did the participants' safety results change during the study?

To answer this question, the researchers compared the results of the following tests and measurements. These were done before the study and throughout the study:

- physical examinations
- blood and urine tests
- ECGs

At the end of the study, the researchers found that there were some changes in the results of these measurements. But overall, the researchers did not find these changes to be significant.

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. A lot of research is needed to know whether a treatment causes an adverse event.

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

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

None of the participants died during the study.

Adverse events

There were 52.5% of participants who had adverse events during the study. This was 32 out of 61 participants. The table below shows how many participants had adverse events during the study.

Adverse events

	Group 1 Lowest dose of MEDI0382 (Out of 15 participants)	Group 2 Middle dose of MEDI0382 (Out of 15 participants)	Group 3 Highest dose of MEDI0382 (Out of 15 participants)	Group 4 Placebo (Out of 16 participants)
How many participants had adverse events?	40.0% (6)	73.3% (11)	60.0% (9)	37.5% (6)
How many participants had serious adverse events?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment due to adverse events?	0.0% (0)	26.7% (4)	6.7% (1)	0.0% (0)

Most common adverse events

The most common adverse event that happened during the study was nausea.

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

	Group 1 Lowest dose of MEDI0382 (Out of 15 participants)	Group 2 Middle dose of MEDI0382 (Out of 15 participants)	Group 3 Highest dose of MEDI0382 (Out of 15 participants)	Group 4 Placebo (Out of 16 participants)
Nausea	13.3% (2)	46.7% (7)	26.7% (4)	6.3% (1)
Vomiting	20.0% (3)	33.3% (5)	20.0% (3)	0.0% (0)
Decreased appetite	0.0% (0)	20.0% (3)	13.3% (2)	0.0% (0)
Feeling unwell in general	0.0% (0)	0.0% (0)	20.0% (3)	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 treatments. A lot of research is needed to know whether a treatment causes an adverse reaction.

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

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

How many participants had adverse reactions?

There were 39.3% of participants who had adverse reactions during the study. This was 24 out of 61 participants. The table below shows how many participants had adverse reactions during the study.

Adverse reactions

	Group 1 Lowest dose of MEDI0382 (Out of 15 participants)	Group 2 Middle dose of MEDI0382 (Out of 15 participants)	Group 3 Highest dose of MEDI0382 (Out of 15 participants)	Group 4 Placebo (Out of 16 participants)
How many participants had adverse reactions?	33.3% (5)	53.3% (8)	53.3% (8)	18.8% (3)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment due to adverse reactions?	0.0% (0)	20.0% (3)	6.7% (1)	0.0% (0)

What adverse reactions did the participants have?

The most common adverse reaction during the study was nausea.

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

	Group 1 Lowest dose of MEDI0382 (Out of 15 participants)	Group 2 Middle dose of MEDI0382 (Out of 15 participants)	Group 3 Highest dose of MEDI0382 (Out of 15 participants)	Group 4 Placebo (Out of 16 participants)
Nausea	13.3% (2)	46.7% (7)	20.0% (3)	6.3% (1)
Vomiting	20.0% (3)	20.0% (3)	20.0% (3)	0.0% (0)
Decreased appetite	0.0% (0)	20.0% (3)	13.3% (2)	0.0% (0)
Feeling unwell in general	0.0% (0)	0.0% (0)	20.0% (3)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn how MEDI0382 affects blood sugar and weight in people who have type 2 diabetes, and if MEDI0382 is safe to take.

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 MEDI0382 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 **"NCT03645421"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5674C00001"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase IIa, Randomised, Parallel, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of MEDI0382 in Japanese Preobese or Obese Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control with Diet and Exercises

AstraZeneca Protocol Number: D5674C00001

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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