Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune Limited

Drug Studied: MEDI0382

Study Title: A study to learn how MEDI0382 affects the blood sugar levels and weight of overweight and obese patients with type 2 diabetes

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI0382. All of the participants helped researchers learn more about MEDI0382 to help patients with type 2 diabetes.

MedImmune Limited 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 participants were in the study for about 4.5 months. But, the entire study took about 5 months to finish.

The study started in September 2017 and ended in January 2018. It included 65 participants in Germany.

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 overweight and obese patients with type 2 diabetes. 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 find out if MEDI0382 works in a small number of overweight and obese participants with type 2 diabetes. They also wanted to find out if the participants had any medical problems during the study.

In patients with type 2 diabetes who are obese or overweight, a hormone known as insulin does not work as well as it should. The body creates insulin to help control the levels of sugar in the blood. The study drug MEDI0382 might help keep the body's blood sugar levels normal. MEDI0382 might also help reduce a person's appetite and increase the number of calories he or she burns, which could help with weight loss.

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

- How did MEDI0382 affect the blood sugar levels and weight of the participants?
- What medical problems did the participants have during the study?

To answer the questions in this study, researchers asked for the help of overweight and obese men and women with type 2 diabetes. The participants in this study were 43 to 74 years old.

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 received. Some studies are done this way because knowing what treatment the participants are given can affect the results of the study. When the study ended, the research sponsor found out which treatment the participants took so they could create a report of the study results.

The participants in this study were given 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 take a drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant was given. 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 treatment, the study doctors:

- did a physical examination
- took blood and urine samples
- checked the heart health of the participants using an electrocardiogram, also called an ECG
- checked the blood sugar levels and weight of the participants
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

During treatment, there were 2 treatment groups. Participants in both groups were given either MEDI0382 or a placebo through a needle under the skin. There were 39 participants in Group 1 and 26 participants in Group 2.

Throughout the treatment period, the researchers checked all participants' blood sugar levels and weight and asked them how they were feeling.

In Group 1, 26 participants were given MEDI0382 and 13 participants were given the placebo. The MEDI0382 doses were measured in micrograms, also called µg. The participants visited their study site 8 times over the course of 7 weeks and were given the below doses in order:

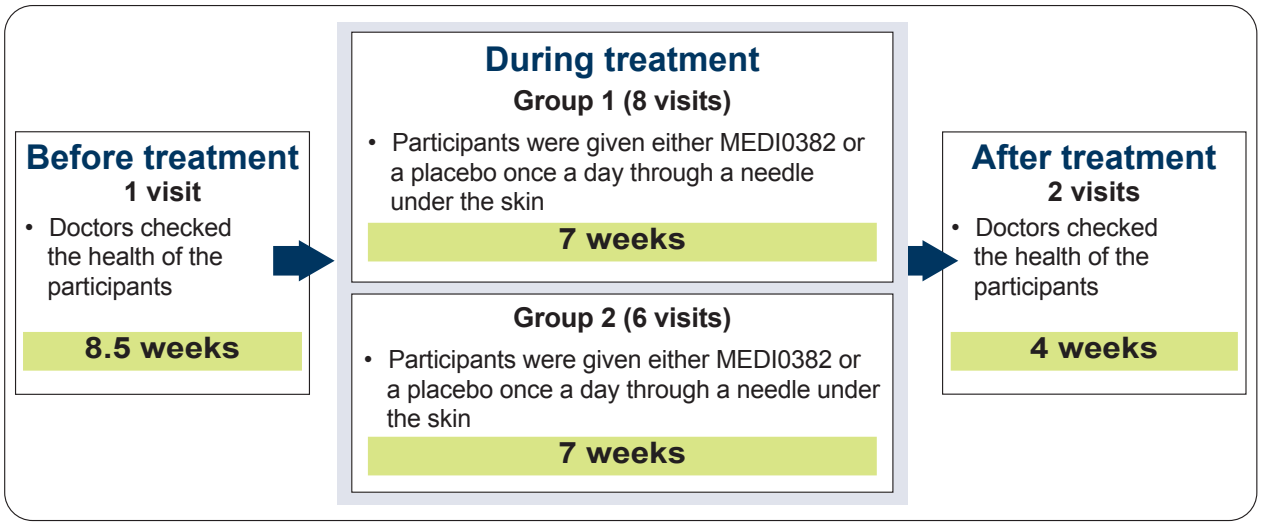
- 50 µg of MEDI0382 or the placebo once a day for 1 week
- 100 µg of MEDI0382 or the placebo once a day for 1 week
- 200 µg of MEDI0382 or the placebo once a day for 1 week
- 300 µg of MEDI0382 or the placebo once a day for 4 weeks

In Group 2, 20 participants were given MEDI0382 and 6 participants were given the placebo. The participants visited their study site 6 times over the course of 7 weeks and were given the below doses in order:

- 50 µg of MEDI0382 or the placebo once a day for 2 weeks
- 100 µg of MEDI0382 or the placebo once a day for 2 weeks
- 200 µg of MEDI0382 or the placebo once a day for 2 weeks
- 300 µg of MEDI0382 or the placebo once a day for 1 week

After treatment, all of the participants visited their study site 2 times. During these visits, the researchers checked the participants' blood sugar levels and weight again and asked them how they were feeling.

The chart below shows how the study was done.



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.

The first question the researchers wanted to answer in this study was focused on the Group 1 treatment schedule. So, the results for the first question below are only for Group 1 participants.

How did MEDI0382 affect the blood sugar levels and weight of the participants?

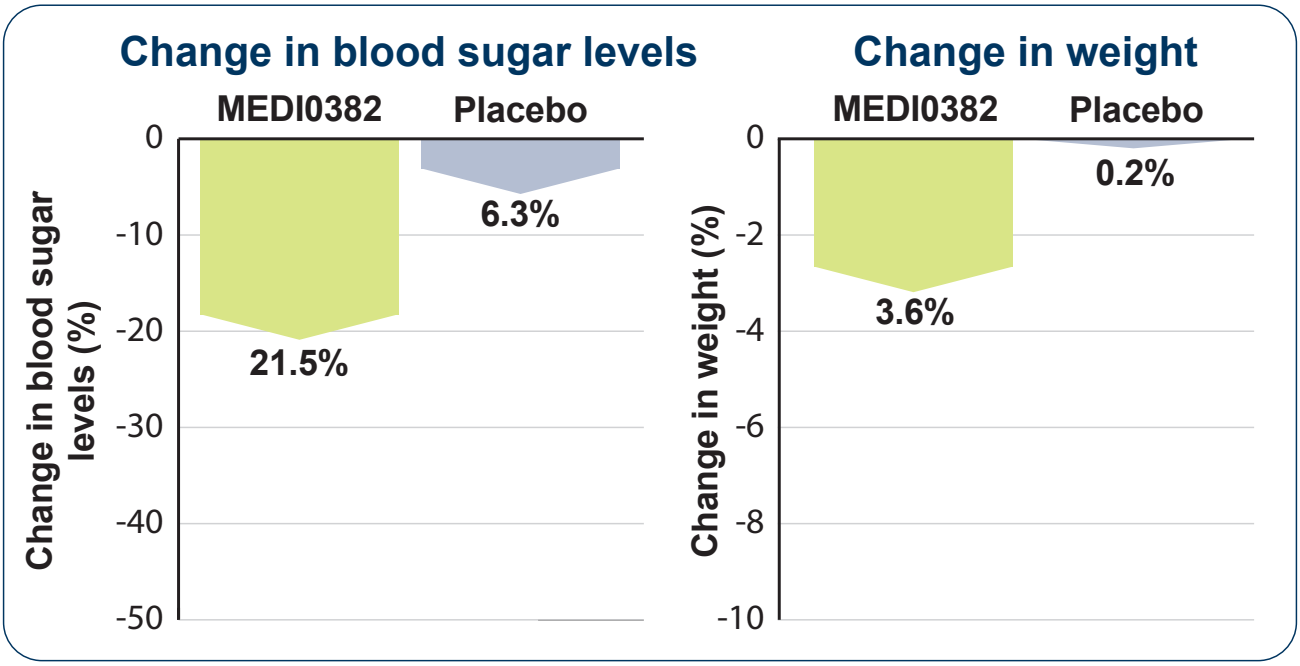
In Group 1, the researchers found there was a larger decrease in blood sugar levels and weight in the participants who were given MEDI0382 compared to the participants who were given the placebo.

To answer this question, the researchers measured the blood sugar levels and weight of Group 1 participants before and after study treatment. Then, the researchers compared these measurements.

The researchers found that:

- The participants who were given MEDI0382 had a 21.5% decrease in blood sugar levels.
- The participants who were given the placebo had a 6.3% decrease in blood sugar levels.
- The participants who were given MEDI0382 had a 3.6% decrease in weight.
- The participants who were given the placebo had a 0.2% decrease in weight.

The figure below shows these results.



What medical problems did the participants have during the study?

This section is a summary of the medical problems that both Group 1 and Group 2 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.

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.

How many participants had serious adverse reactions?

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

None of the participants died during the study.

How many participants had adverse reactions?

There were 50.8% of participants who had adverse reactions during the study. This was 33 out of 65 participants.

There were 1.5% of participants who stopped taking MEDI0382 because of an adverse reaction they had during the study. This was 1 out of 65 participants.

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

Adverse reactions during the study

	MEDI0382 Group 1 (out of 26 participants)	Placebo Group 1 (out of 13 participants)	MEDI0382 Group 2 (out of 20 participants)	Placebo Group 2 (out of 6 participants)
How many participants had adverse reactions during the study?	65.4% (17)	15.4% (2)	70.0% (14)	0.0% (0)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment because of adverse reactions?	0.0% (0)	0.0% (0)	5.0% (1)	0.0% (0)

What adverse reactions did the participants have?

The most common adverse reaction was decreased appetite.

The table below shows the adverse reactions that happened in at least 2 participants in either of the MEDI0382 groups during the study. There were other adverse reactions, but these happened in fewer participants. Some of the participants had more than 1 adverse reaction.

Most common adverse reactions

	MEDI0382 Group 1 (out of 26 participants)	Placebo Group 1 (out of 13 participants)	MEDI0382 Group 2 (out of 20 participants)	Placebo Group 2 (out of 6 participants)
Decreased appetite	50.0% (13)	15.4% (2)	0.0% (0)	0.0% (0)
Nausea	15.4% (4)	0.0% (0)	30.0% (6)	0.0% (0)
Vomiting	11.5% (3)	0.0% (0)	20.0% (4)	0.0% (0)
Bloating	15.4% (4)	0.0% (0)	10.0% (2)	0.0% (0)
Constipation	15.4% (4)	0.0% (0)	5.0% (1)	0.0% (0)
Headache	7.7% (2)	0.0% (0)	15.0% (3)	0.0% (0)
Reddening of the skin at injection site	0.0% (0)	0.0% (0)	25.0% (5)	0.0% (0)
Belching	11.5% (3)	0.0% (0)	0.0% (0)	0.0% (0)
Diarrhea	7.7% (2)	0.0% (0)	5.0% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about how MEDI0382 affects the blood sugar levels and weight of overweight and obese patients with type 2 diabetes.

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 **"NCT03244800"** into the **"Other Terms"** search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2017-002025-38"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5670C00011"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 2, Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, Tolerability, and Pharmacokinetics of Different Doses of MEDI0382 in Overweight and Obese Subjects with Type 2 Diabetes Mellitus

AstraZeneca Protocol number: D5670C00011

MedImmune Limited, a wholly owned subsidiary of AstraZeneca, 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 participants.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

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 patients for clinical studies, nor is it involved in conducting clinical studies.

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