Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research sponsor: MedImmune, Ltd

Drug studied: MEDI0382

Short study title: A study to learn how MEDI0382 affects the blood sugar levels and weight of overweight and obese people with type 2 diabetes

Thank you!

Thank you for taking part in the clinical study for the study drug MEDI0382. You and all of the participants helped researchers learn more about if MEDI0382 can help overweight and obese people with type 2 diabetes.

MedImmune, Ltd sponsored this study and thinks 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 doctor or staff at your study site.

What is happening with the study now?

This study had 3 parts, called Part A, Part B, and Part C. This summary discusses the results for Part B only. This is because the main questions and results the researchers wanted to study were in Part B.

The participants in Part B were in the study for up to 17 weeks. But, the entire study took a little more than 1 year to finish.

The overall study started in December 2015 and ended in February 2017. Part B of the study included 51 participants in Germany.

The sponsor reviewed the data collected when Part B of 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 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 can help overweight and obese people with type 2 diabetes to control their blood sugar levels and lose weight. They also wanted to find out if the participants had any medical problems when they were given the treatments.

In people with type 2 diabetes, the body cannot control the levels of sugar in the blood, which can lead to several medical problems. In many cases, the cause of type 2 diabetes is being overweight or obese, but few of the current type 2 diabetes treatments help people to lose weight. The researchers in this study wanted to learn if MEDI0382 can help the body control blood sugar levels and also help people lose weight.

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

- How did MEDI0382 affect the blood sugar levels and weight of participants?
- What medical problems did the participants have when they were given each treatment?

To answer the questions in this study, the researchers asked for the help of overweight or obese men and women with type 2 diabetes. The participants in Part B were 41 to 65 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 was given. Some studies are done this way because knowing what treatment the participants are getting can affect the results of the study. When the study ended, MedImmune found out which treatment the participants were given so they could create a report of the study results.

In Part B of this study, the participants were given either MEDI0382 or a placebo as an injection under the skin. A placebo looks like the 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 the drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant was given. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

Before the study started, the doctors did a physical examination to make sure the participants could join the study. They also took blood and urine samples and checked the heart health of the participants using an electrocardiogram, also known as an ECG.

During Part B of the study, the participants were given either MEDI0382 or a placebo once a day as an injection under the skin.

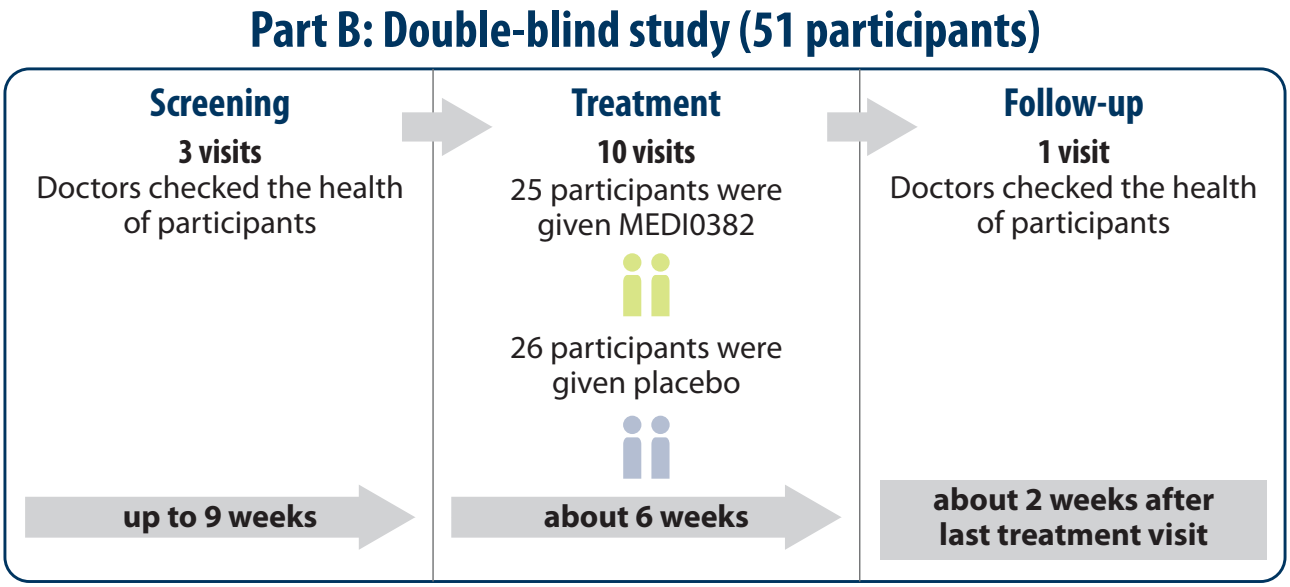
The participants getting MEDI0382 were given the below treatments in order:

- 100 micrograms, also called µg, for 4 days at their study site
- 150 µg for 4 days at their study site
- 200 µg for 4 days at their study site
- 200 µg for 28 days at home
- 200 µg for 1 day at their study site

The participants getting the placebo were given their treatment in the same way as the participants who were given MEDI0382.

At the end of Part B of the study, the participants visited their study site for a follow-up examination so the doctors could check their health again.

The figure below shows how Part B of the study was done.



What were the results of the study?

This is a summary of the main results from Part B of this study. The results for each individual participant 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.

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

The researchers compared the blood sugar levels and weight of participants from the start of Part B to their blood sugar levels and weight at the end of Part B.

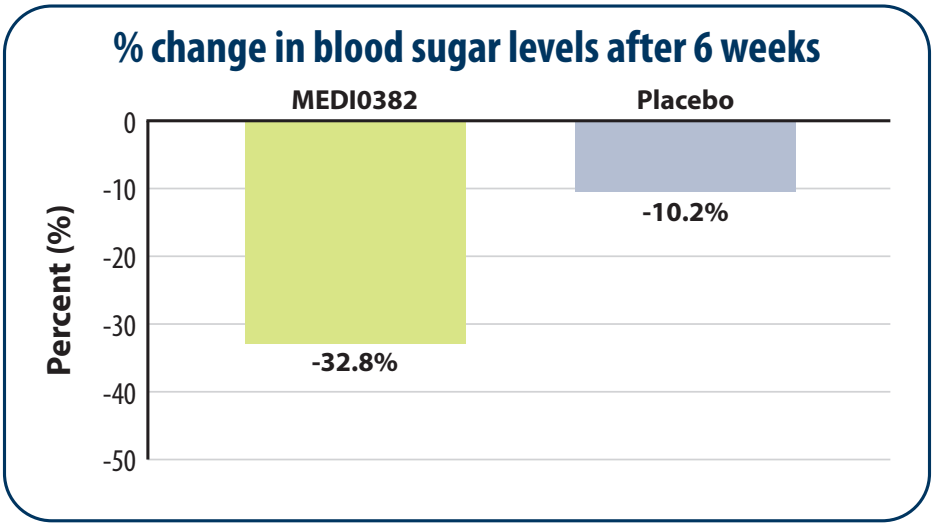
To do this, the researchers used a scientific method called the “least square mean” to calculate the results. The least square mean method takes missing or incomplete data that could cause results to be inaccurate into account. Researchers use this method to make sure study results are more accurate.

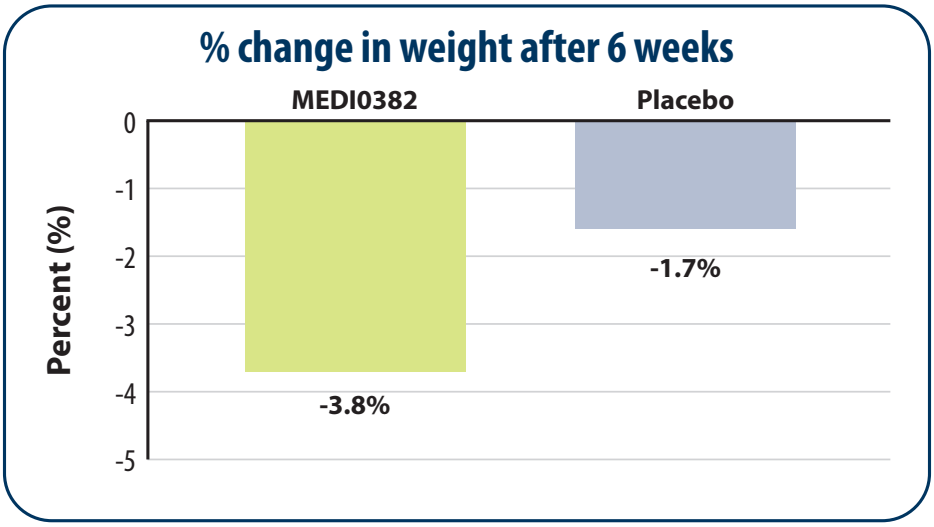
At the end of the study, the researchers found that the blood sugar levels and weight of the participants who were given MEDI0382 decreased more than those of the participants who were given the placebo.

In general, after about 6 weeks of treatment in Part B:

- the participants who were given MEDI0382 after fasting for a minimum of 8 hours had a 32.8% decrease in their blood sugar levels
- the participants who were given the placebo after fasting for a minimum of 8 hours had a 10.2% decrease in their blood sugar levels
- the participants who were given MEDI0382 had a 3.8% decrease in their weight
- the participants who were given the placebo had a 1.7% decrease in their weight

The figures below show these results.





What medical problems did the participants have?

This section is a summary of the medical problems the participants had during Part B of the study that the 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 more information about the adverse reactions or other medical problems that happened in this study.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

There were 68.6% of the participants who had adverse reactions during Part B of the study. This was 35 out of 51 participants.

There were 7.8% of the participants who stopped treatment during Part B because of adverse reactions they had during the study. This was 4 out of 51 participants.

None of the participants died during Part B of the study.

What adverse reactions did the participants have?

The most common adverse reaction during Part B was nausea.

The adverse reactions in the table below happened in at least 20.0% of the participants in either treatment group. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions during Part B

	MEDI0382 (out of 25 participants)	Placebo (out of 26 participants)
Nausea	44.0% (11)	19.2% (5)
Headache	28.0% (7)	7.7% (2)
Vomiting	32.0% (8)	0.0% (0)
Constipation	20.0% (5)	7.7% (2)
Bloating in stomach	24.0% (6)	0.0% (0)
Indigestion	20.0% (5)	3.8% (1)
Decreased appetite	20.0% (5)	0.0% (0)
Tiredness	20.0% (5)	0.0% (0)

How has this study helped patients and researchers?

The results presented here are for a single study. These results helped the researchers learn how MEDI0382 affects the blood sugar levels and weight in overweight patients with type 2 diabetes.

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.

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 **"NCT02548585"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home & Search"**, then type **"2014-003716-36"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5670C00002"** into the search box, and click **"Find a Study"**.

Official study title: A Phase1/2, Randomized, Blinded, Placebo-controlled, Multiple-ascending-dose Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MEDI0382 in Overweight and Obese Subjects with a History of Type 2 Diabetes Mellitus

Protocol number: D5670C00002

MedImmune, Ltd, a member of the AstraZeneca Group of companies and has its headquarters at Milstein Building, Granta Park, Cambridge CB21 6GH.

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.