Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, Ltd.

Drug Studied: MEDI0382

Study Title: A study to learn about the safety of MEDI0382 in participants of Japanese and Chinese descent who were overweight or had obesity

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug MEDI0382. MedImmune Ltd., an AstraZeneca company, sponsored this study and thinks 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 doctor or staff at your study site.

What is happening with the study now?

The participants were in the study for up to 9 weeks. The study started in January 2018 and ended in April 2018.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

The study included 32 participants from the United States. Of these, 24 participants were of Japanese descent and 8 were of Chinese descent.

Why was the research needed?

Researchers are looking for a better way to treat patients with type 2 diabetes mellitus, also called T2DM. Before a treatment can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

T2DM is a common condition that causes the levels of blood sugar to rise higher than normal. This often happens in people who are overweight and do not exercise.

MEDI0382 is being developed to treat T2DM. It is designed to act like hormones in the body that control blood sugar levels and appetite. There are treatments available for T2DM that focus on lowering blood sugar levels, but most of these do not reduce appetite. Researchers think that MEDI0382 might help treat T2DM by lowering blood sugar levels and reducing appetite. Reducing appetite may help with weight loss, which can be helpful for people with T2DM.

In this study, the researchers wanted to find out about the safety of MEDI0382 in participants who were overweight who did not have T2DM. The main questions the researchers wanted to answer in this study were:

- Did MEDI0382 affect the participants' safety?
- 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 that help find out if MEDI0382 improves the health of people with T2DM.

The researchers asked for the help of healthy men and women who were overweight or obese and who were of Japanese or Chinese descent. Everyone in the study was between 27 and 59 years old.

What kind of study was this?

This was a "double-blind" study. This means neither the participants nor the study doctor knew which treatment the participants got.

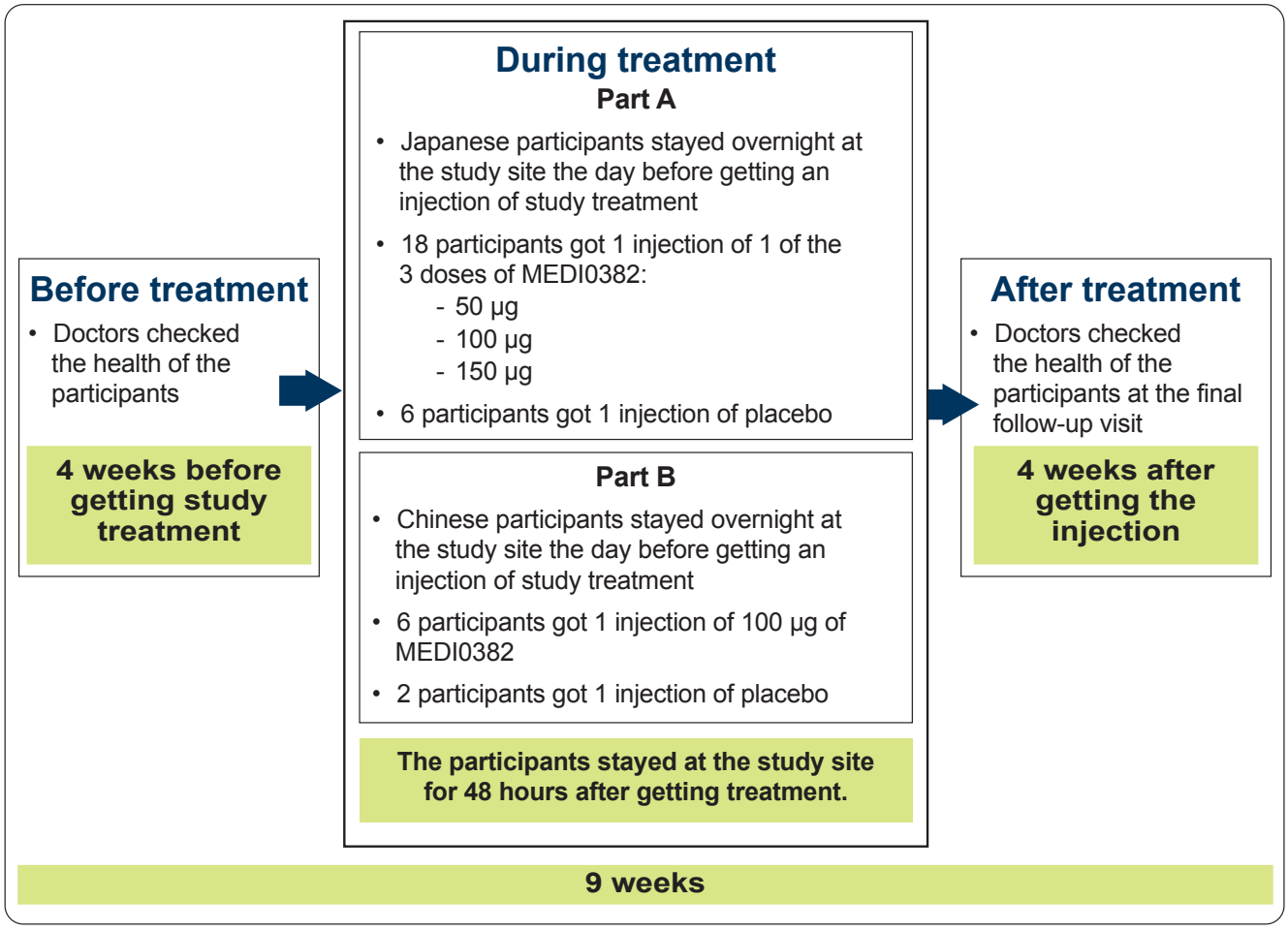
A computer program was used to randomly choose the treatment each participant got. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

In this study, the participants got 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 treatment are actually caused by the treatment.

Both MEDI0382 and the placebo were given as injections under the skin. The doses of MEDI0382 were measured in micrograms, also called µg. The participants could get 1 of the following doses of MEDI0382: 50 µg, 100 µg, or 150 µg. Originally, the researchers planned for some participants to get a dose of 200 µg, but researchers decided not to continue with this part of the study and did not recruit any participants to get this dose of MEDI0382.

What happened during the study?

This study had 2 parts, Part A and Part B. In each part, the participants got either MEDI0382 or a placebo. The diagram below shows how the study was done. Part B of the study happened after participants in Part A had received the 100 µg dose of MEDI0382. The study was designed to have 4 groups in Part A, but the researchers decided to not recruit the last group. Part B only had 1 group of participants. This group got the 100 µg dose because the researchers did not expect there to be any meaningful differences in study results between participants of Japanese or Chinese descent. The researchers thought that only 1 treatment group would be enough to check this.



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.

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 change.

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

Did MEDI0382 affect the participants' safety results?

Overall, the researchers found that MEDI0382 did not affect the participants' safety results differently than other drugs of this type compared to the placebo.

To answer this question, the doctors did tests and took measurements at different times after the participants got an injection of study treatment. The doctors:

- asked the participants about their health and any medications they were taking
- took blood and urine samples
- did physical examinations
- tested the participants' breathing
- studied vital signs
- did electrocardiograms, also called ECGs, to check the participants' heart health

The researchers found that:

- The Japanese participants who got 100 µg or 150 µg of MEDI0382 had a slight increase in their heart rate 48 hours after getting MEDI0382
- The Chinese participants who got 100 µg of MEDI0382 had a slight increase in their heart rate 48 hours after getting MEDI0382

But, the differences between these groups and the groups that got a placebo were too small for the researchers to know if MEDI0382 caused the increased heart rate.

The researchers also found that participants who received the 150 µg dose were more likely to have nausea or vomiting than the participants who got the placebo.

The researchers did not find any other differences in the safety results of the participants who got MEDI0382 and the participants who got a placebo.

What medical problems did participants have during the 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 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.

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?

In this study, none of the participants had a serious adverse reaction.

How many participants had adverse reactions?

Overall, there were 28.1% of participants who had an adverse reaction during the study. This was 9 out of 32 participants.

There were 29.2% of Japanese participants who had an adverse reaction during the study. This was 7 out of 24 participants.

There were 25.0% of Chinese participants who had an adverse reaction during the study. This was 2 out of 8 participants.

None of the participants left the study due to an adverse reaction.

What adverse reactions did the participants have?

The most common adverse reactions in this study were nausea and vomiting. The table below shows the adverse reactions that occurred in 1 or more participants of Japanese or Chinese descent who got MEDI0382.

Adverse reactions during the study

Adverse reaction	Japanese participants (50 µg MEDI0382) 6 participants	Japanese participants (100 µg MEDI0382) 6 participants	Japanese participants (150 µg MEDI0382) 6 participants	Japanese participants (placebo) 6 participants	Chinese participants (100 µg MEDI0382) 6 participants	Chinese participants (placebo) 2 participants
Nausea	0.0% (0)	0.0% (0)	83.3% (5)	16.7% (1)	0.0% (0)	0.0% (0)
Vomiting	0.0% (0)	0.0% (0)	66.7% (4)	16.7% (1)	16.7% (1)	0.0% (0)
Headache	0.0% (0)	0.0% (0)	66.7% (4)	16.7% (1)	16.7% (1)	0.0% (0)
Vertigo, which is a kind of dizziness	0.0% (0)	0.0% (0)	16.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Heart skips a beat	0.0% (0)	0.0% (0)	16.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Dizziness	16.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

How has this study helped patients and researchers?

These results helped researchers learn how MEDI0382 works in people of Japanese or Chinese descent who are overweight or obese.

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.

The study found that since the safety results for this group was similar to other groups who have taken the drug, future studies with MEDI0382 can include Japanese and Chinese participants.

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 **"NCT03385369"** into the **"Other Terms"** search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5670C00012"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 1, Randomized, Blinded, Single Ascending Dose Study to Evaluate the Safety and Pharmacokinetics of MEDI0382 in Overweight/Obese Subjects of Japanese or Chinese Descent

National Clinical Trials number: NCT03385369

AstraZeneca Protocol Number: D5670C00012

MedImmune Ltd., an AstraZeneca company, sponsored this study and has its headquarters in Gaithersburg, United States.

The phone number for the AstraZeneca Information Center is +1 877 240 9479.

Thank you!

Clinical trial 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 (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.

CISCRP
One Liberty Square, Suite 1100
Boston, MA 02109

1-877-MED-HERO