Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, a wholly owned subsidiary of AstraZeneca

Drugs Studied: MEDI0382

Study Title: A study to find out about the safety of MEDI0382 in participants with obesity

Thank you!

Thank you for taking part in the clinical study for the study drug MEDI0382.

MedImmune 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 the study?

The researchers asked for the help of men and women who have obesity. The participants in this study were 19 to 64 years old when they joined and did not have diabetes or other serious health problems.

The study included 51 participants in the United States.

Why was the research needed?

Researchers are looking for a better way to help people who have obesity. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

Some people with obesity may have a hard time losing weight through lifestyle changes alone and may need extra help from medical treatments. Obesity can lead to serious problems such as heart disease or type 2 diabetes.

Researchers think MEDI0382 can reduce appetite and slow digestion, which helps people feel full for longer. This may help people to lose weight.

In this study, the researchers wanted to find out about the safety of MEDI0382 in participants with obesity.

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 during the study?
- 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 MEDI0382 helps improves the health of people who have obesity.

What treatments did the participants take?

This was a “double-blind” study. This means none of the participants, researchers, study doctors, or other study staff knew what treatment each participant was taking. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. When the study ended, the research sponsor created a report of the study results.

There were 3 different treatment groups in this study. In each group, the participants took either MEDI0382 or a placebo once a day as an injection under the skin. 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 the drug are actually caused by the drug.

Overall, 36 participants took MEDI0382 and 15 participants took a placebo:

- In Group 1, 12 participants took MEDI0382 and 3 participants took a placebo.
- In Group 2, 12 participants took MEDI0382 and 6 participants took a placebo.
- In Group 3, 12 participants took MEDI0382 and 6 participants took a placebo.

A computer program was used to randomly choose the treatment each participant took. 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 participants who took MEDI0382 took increasing doses throughout the study. The doses were measured in micrograms, also known as µg.

In Group 1, the doses were:

Week	1	2	3	4	5	6	7	8	9
Dose	50 µg	100 µg	200 µg	300 µg	400 µg	500 µg	600 µg	600 µg	600 µg

In Group 2, the doses were:

Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Dose	50 µg	50 µg	100 µg	100 µg	200 µg	200 µg	400 µg	400 µg	600 µg	600 µg	600 µg	600 µg	600 µg	600 µg

In Group 3, the doses were:

Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Dose	50 µg	50 µg	50 µg	50 µg	150 µg	150 µg	150 µg	150 µg	300 µg	300 µg	300 µg	300 µg	600 µg	600 µg	600 µg	600 µg	600 µg	600 µg

What happened during the study?

The study started in August 2018 and ended in August 2019.

Before the participants took study treatment, they visited their study site 2 times. At these visits, the study doctors checked the health of the participants to make sure they could join the study. This part of the study lasted up to 5 weeks. The study doctors:

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

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

At these visits, the study doctors showed the participants how to give themselves injections using a saltwater injection, also called saline. The participants met with a dietician who gave them diet and exercise advice.

The participants in Group 1 also started wearing a device to measure their blood sugar, called a continuous glucose monitoring device. This is known as a CGM device.

While the participants took study treatment, they:

- stayed overnight at their study site for several of their study visits
- received phone calls from the study doctors at home between study visits
- gave themselves 1 injection of MEDI0382 or the placebo every day
- kept a diary of their symptoms and wore their CGM device

The participants in:

- **Group 1** visited their study site 16 times over 9 weeks
- **Group 2** visited their study site 15 times over 14 weeks
- **Group 3** visited their study site 17 times over 18 weeks

After the participants took study treatment, they visited their study site 1 time about 4 weeks after their last dose.

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.

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

To answer this question, the study doctors did tests and measurements before and after the participants took study treatment.

The study doctors:

- did physical exams
- tested the participants' blood and urine samples
- did ECGs to check the participants' heart health

Overall, the researchers found that there were some small changes in the results of these tests and measurements. But, the researchers did not consider these to be significant.

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 treatment. This section is a summary of all the adverse events, whether they might be related to the study treatment 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.

	MEDI0382 (out of 36 participants)	**Placebo (out of 15 participants)**
How many participants had adverse events?	88.9% (32)	93.3% (14)
How many participants had serious adverse events?	0.0% (0)	0.0% (0)
How many participants stopped taking study treatment because of adverse events?	19.4% (7)	6.7% (1)

The most common adverse events during the study were:

- Constipation
- Diarrhea
- Headache
- Low appetite
- Nausea
- Vomiting

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 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the drug.

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.

	MEDI0382 (out of 36 participants)	Placebo (out of 15 participants)
How many participants had adverse reactions?	83.3% (30)	60.0% (9)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)
How many participants stopped taking study treatment because of adverse reactions?	19.4% (7)	0.0% (0)

What adverse reactions happened during this study?

The most common adverse reaction was nausea.

The table below shows the most common adverse reactions that happened in 10 or more participants in total during the study. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions during the study

Adverse reaction	MEDI0382 (out of 36 participants)	Placebo (out of 15 participants)
Nausea	69.4% (25)	26.7% (4)
Low appetite	55.6% (20)	26.7% (4)
Vomiting	47.2% (17)	6.7% (1)
Headache	25.0% (9)	20.0% (3)
Diarrhea	22.2% (8)	20.0% (3)

How has this study helped people and researchers?

This study helped researchers learn more about the safety of MEDI0382 in participants with obesity.

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.

Other 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 more information about the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03625778"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5672C00001"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Randomized, Blinded, Placebo-controlled Study to Assess Pharmacokinetics, Safety and Tolerability of Ascending Doses of MEDI0382 in Non-diabetic Obese Subjects

MedImmune Protocol Number: D5672C00001

National Clinical Trials number: NCT03625778

MedImmune, a wholly owned subsidiary of AstraZeneca, sponsored this study and has its headquarters in Cambridge, UK.

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.

CISCRP
One Liberty Square, Suite 1100 • Boston, MA 02109
1-877-MED-HERO • www.ciscrp.org