

**Research Sponsor:** MedImmune, an AstraZeneca company

**Drug Studied:** MEDI0382

**Study Title:** A study to learn how MEDI0382 affects blood sugar levels in people who have type 2 diabetes

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## ***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.

MedImmune, an AstraZeneca company, 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 up to about 5 months. But the entire study took about 7 months to finish.

The study started in May 2018 and ended in December 2018. It included 49 participants in Germany and Hungary.

When the study ended, the sponsor reviewed the data collected 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 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 find out how MEDI0382 affects the blood sugar levels in participants who have type 2 diabetes and are overweight or have obesity.

These participants were also taking either metformin alone or metformin and dapagliflozin together. Both of these treatments are commonly used by doctors to help people who have type 2 diabetes control their disease. In people who have type 2 diabetes, the body does not respond to 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.

Metformin works by decreasing the amount of blood sugar that the liver releases and makes the body better respond to insulin. Dapagliflozin works by helping the body remove sugar through the urine. But, these drugs taken together may not help some people who have type 2 diabetes. They may also cause medical problems in some people.

The study drug, MEDI0382, is being developed to increase the body's ability to make insulin. Researchers think that MEDI0382 taken with metformin and dapagliflozin may help people who have type 2 diabetes control their blood sugar levels.

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

- Did MEDI0382 help lower the participants' blood sugar levels?
- What medical problems did the participants have during the study?

To answer these questions, the researchers asked for the help of men and women who had type 2 diabetes and were overweight or had obesity. These participants were already taking either metformin or metformin and dapagliflozin together. The participants in this study were 41 to 74 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. 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, the research sponsor found out which treatment the participants got so they could create a report of the study results.

In this study, the participants got either MEDI0382 or a placebo through a needle under the skin, also called an injection. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure that any of the effects they see in the participants who get the study drug are caused by the study drug. The MEDI0382 doses were measured in micrograms, also called µg.

All of the participants were taking either metformin or metformin and dapagliflozin together before the study started. During the study, the participants took both metformin and dapagliflozin as tablets by mouth.

A computer program was used to randomly choose the study 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 1 time over the course of about 2 months. During this visit, 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' blood sugar levels
- checked the participants' heart health using an electrocardiogram, also called an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

**During the study,** the participants visited their study site 10 times over the course of about 2 months. During this time, the study doctors checked the participants' overall health and blood sugar levels, and asked them how they were feeling.

The participants visited their study site 2 times during the first month. During this time:

- The participants who had been taking only metformin before joining the study began taking dapagliflozin as well.
- The participants who had been taking metformin and dapagliflozin together before joining the study continued taking both drugs.
- The participants did not get any MEDI0382.

During the second month, the participants visited their study site 8 times. During this time, they got 1 of the below treatments each day:

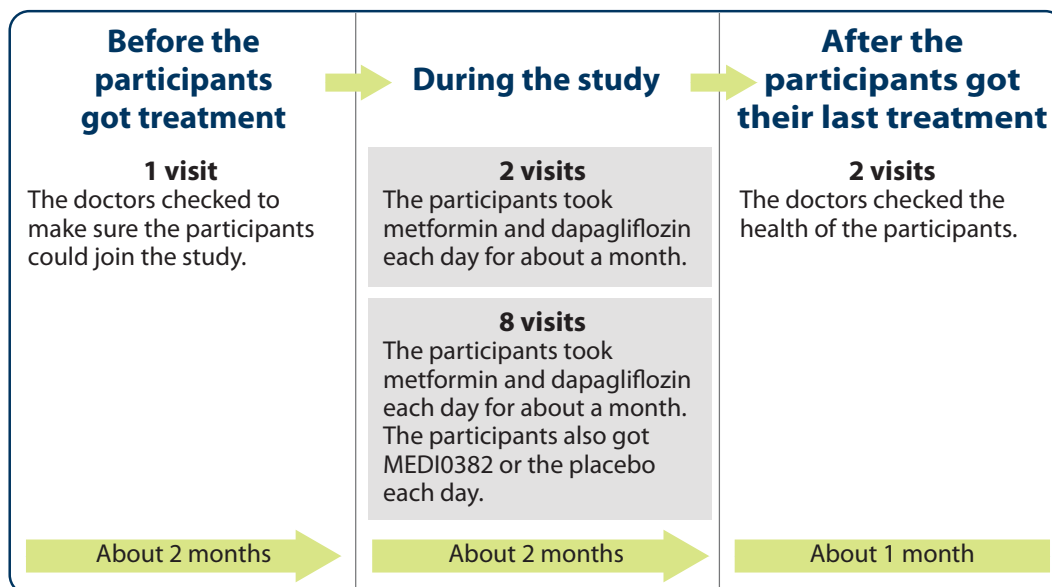
- 25 participants got MEDI0382, metformin, and dapagliflozin
- 24 participants got the placebo, metformin, and dapagliflozin

The participants who got MEDI0382 started out getting a low dose. Once the researchers carefully studied the results for the low dose, they slowly increased the MEDI0382 dose. The participants who got MEDI0382 received these doses:

- 100 µg of MEDI0382 each day for 1 week
- 200 µg of MEDI0382 each day for 1 week
- 300 µg of MEDI0382 each day for 2 weeks

**After the participants got their last treatment**, they visited their study site 2 times over the course of about 1 month. At these visits, the study doctors checked the participants' overall health and blood sugar levels 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.

## Did MEDI0382 help lower the participants' blood sugar levels?

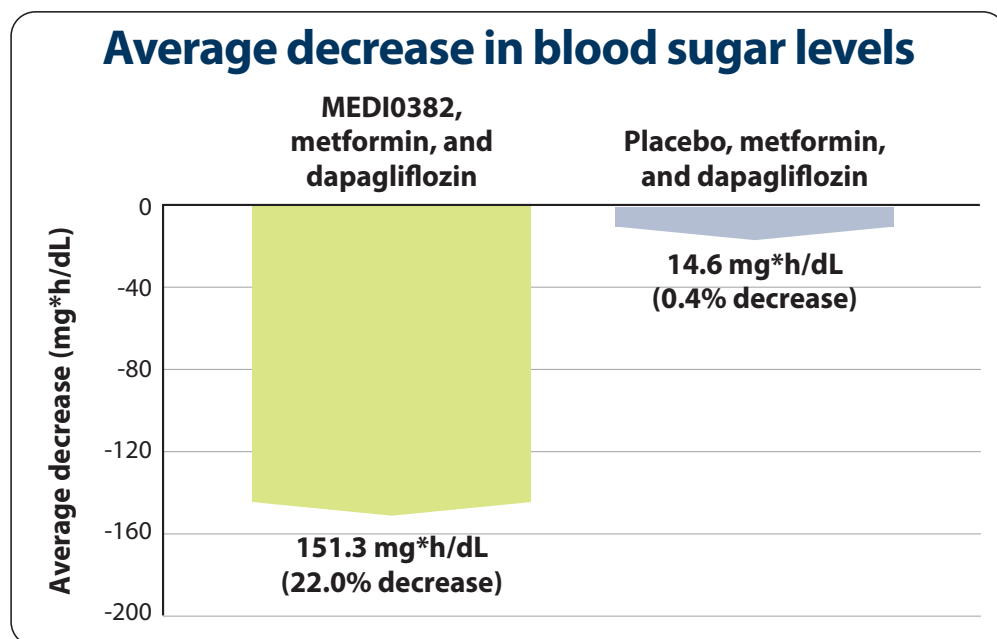
Yes. Overall, the researchers found that the participants who got MEDI0382 had a greater decrease in their blood sugar levels compared to the participants who got the placebo.

To answer this question, the researchers measured the participants' blood sugar levels before they got treatment and throughout the study. Then, they compared the measurements before treatment to the measurements after 1 month of treatment. The blood sugar levels were measured in milligram hours per deciliter, also called  $\text{mg}^*\text{h}/\text{dL}$ .

Overall, the researchers found that after 1 month of study treatment:

- The participants who got MEDI0382, metformin, and dapagliflozin had an average decrease in their blood sugar levels of  $151.3 \text{ mg}^*\text{h}/\text{dL}$ . This was an average decrease of 22.0%.
- The participants who got the placebo, metformin, and dapagliflozin had an average decrease in their blood sugar levels of  $14.6 \text{ mg}^*\text{h}/\text{dL}$ . This was an average decrease of 0.4%.

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 the participants had during the study that the study doctors thought might be related to the study treatment. 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 treatment. 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?

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 40.0% of participants who got MEDI0382 who had adverse reactions during the study. This was 10 out of 25 participants.

There were 16.7% of participants who got the placebo who had adverse reactions during the study. This was 4 out of 24 participants.

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

Adverse reactions during the study		
	MEDI0382, metformin, and dapagliflozin (out of 25 participants)	Placebo, metformin, and dapagliflozin (out of 24 participants)
How many participants had adverse reactions during the study?	40.0% (10)	16.7% (4)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)
How many participants stopped treatment due to adverse reactions?	8.0% (2)	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		
	MEDI0382, metformin, and dapagliflozin (out of 25 participants)	Placebo, metformin, and dapagliflozin (out of 24 participants)
Nausea	20.0% (5)	4.2% (1)
Vomiting	16.0% (4)	0.0% (0)
Constipation	12.0% (3)	0.0% (0)
Headache	8.0% (2)	4.2% (1)
Fast heart beat	4.0% (1)	8.3% (2)
Dizziness	8.0% (2)	0.0% (0)
Pain in upper gut area	8.0% (2)	0.0% (0)
Decreased appetite	4.0% (1)	4.2% (1)
Diarrhea	4.0% (1)	4.2% (1)

## How has this study helped patients and researchers?

This study helped researchers learn how MEDI0382 affects blood sugar levels in people who have type 2 diabetes and are overweight or have 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.

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](http://www.clinicaltrials.gov). Once you are on the website, type “**NCT03444584**” into the search box, and click “**Search**”.
- [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type “**D5670C00007**” into the search box, and click “**Find a Study**”.

**Full study title:** An Exploratory Phase 2a Randomized, Placebo-controlled, Double blind Study to Evaluate the Efficacy and Safety of MEDI0382 versus Placebo in Overweight/Obese Subjects with Type 2 Diabetes Mellitus Treated with Dapagliflozin and Metformin

**AstraZeneca Protocol Number:** D5670C00007

**MedImmune**, an AstraZeneca company, 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.



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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