Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, an AstraZeneca company

Drug Studied: MEDI0382, also called cotadutide

Study Title: A study to find out if MEDI0382 changed the amount of sugar in the blood in participants with type 2 diabetes and kidney problems

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI0382, also called cotadutide. All of the participants helped researchers learn more about MEDI0382 to help people with type 2 diabetes and kidney problems.

MedImmune, an AstraZeneca company, 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?

Participants were in the study for up to 3.5 months, but the entire study took 9 months to finish. The study started in June 2018 and ended in February 2019.

The study included 41 participants from Germany and the United Kingdom.

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 type 2 diabetes, also called T2DM. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

In this study, the researchers wanted to find out if MEDI0382 works in a small number of participants with T2DM and kidney problems. They also wanted to find out if the participants had any medical problems during the study.

T2DM is a condition that causes high levels of blood sugar, also called glucose. In people with T2DM, a hormone called insulin does not work properly. When it works properly, insulin helps keep the blood sugar levels from getting too high. In serious cases, T2DM can lead to long lasting kidney disease and other kidney problems. People with kidney problems may have trouble processing different medications and treatments.

MEDI0382 was designed to lower blood sugar levels by slowing digestion and helping the body to produce more insulin.

In this study, the researchers wanted to find out if MEDI0382 helped lower the amount of glucose in the blood of participants with T2DM and kidney problems.

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

- Did MEDI0382 change the levels of glucose in the blood?
- What medical problems did the participants have during the study?

To answer the questions in this study, the researchers asked for the help of men and women with T2DM. The participants in this study were 57 to 83 years old and had kidney problems.

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 took. 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 found out which treatment participants took so they could create a report of the study results.

In this study, the participants took MEDI0382 or a placebo through a needle under the skin, also called a subcutaneous injection. 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.

The doses of MEDI0382 were measured in micrograms, also known as µg. The participants in the MEDI0382 group took increasing doses over 32 days:

- 50 µg for 4 days
- 100 µg for 7 days
- 200 µg for 7 days
- 300 µg for 14 days

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

In this study, it was planned that 21 participants would take MEDI0382 and 20 participants would take a placebo.

What happened during the study?

Before the participants took the study treatment, the doctors checked the overall health of the participants to make sure that they could join the study. This happened up to 40 days before the participants took study treatment. During this time, the participants visited the study site 3 times. The study staff or doctors:

- did a physical examination
- checked the participants' heart health using an electrocardiogram, also called an ECG
- checked the participants' blood pressure
- took blood samples
- asked about the participants' health and medications
- showed the participants how to give themselves injections of the study treatment

For 14 days before taking study treatment, the participants wore a device to measure their glucose levels. This was called a continuous glucose monitoring device, also called a CGM device.

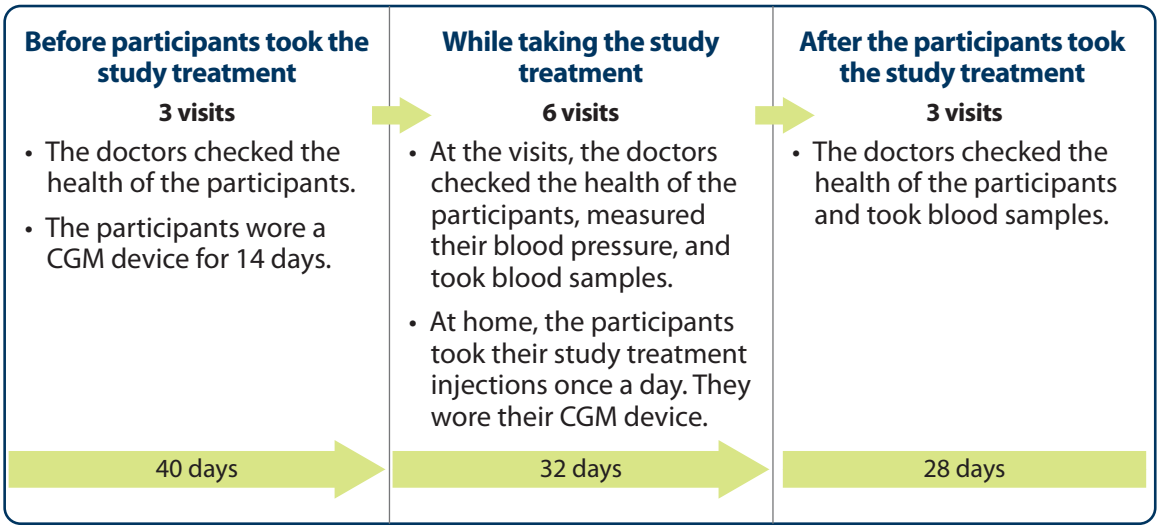
While taking the study treatment, the participants visited the study site 6 times over 32 days. At the first visit, they stayed overnight. At each visit, the doctors:

- checked the overall health of the participants
- checked their blood pressure
- took blood samples

At home, the participants took their injections once a day in the morning and wore their CGM device the whole time.

After taking the study treatment, the participants visited their study site 3 times over 28 days. At these visits, the doctors checked the health of the participants, took blood samples, and asked about any medical problems.

The chart below shows what happened during the study.



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 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.

There was 1 participant who did not finish the study. So, the results below only include information from 40 participants who completed the study.

Did MEDI0382 change the levels of glucose in the blood?

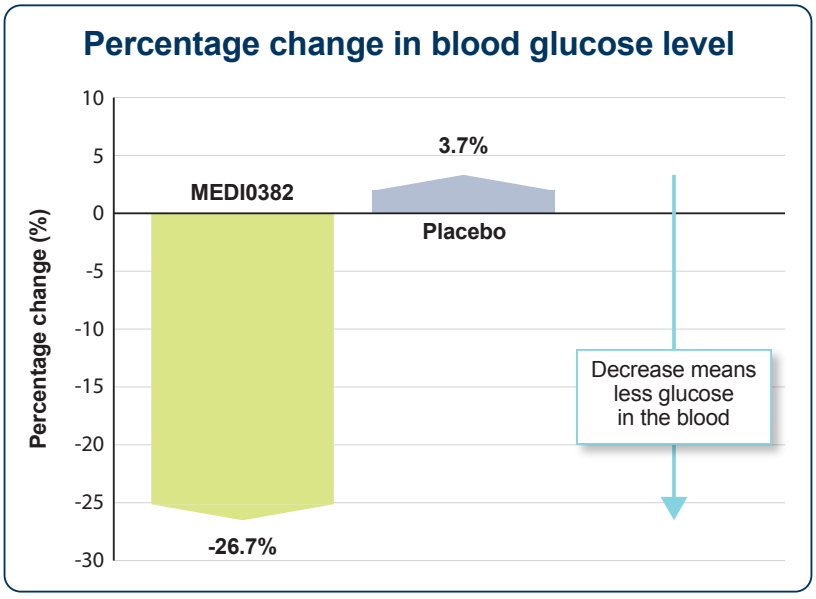
Yes, the researchers found that MEDI0382 changed the participants' blood glucose levels.

To answer this question, the researchers looked at the participants' blood glucose levels before and after they took the study treatment. They measured the average total amount of glucose in the blood 4 hours after the participants ate a meal. The researchers compared the average total amounts of blood glucose for the participants who took MEDI0382 and the participants who took the placebo.

They calculated the average percentage difference between before and after treatment. The researchers found:

- the participants who took MEDI0382 had a 26.7% decrease in average total amounts of blood glucose
- the participants who took the placebo had a 3.7% increase in average total amounts of blood glucose

The chart below shows these results.



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.

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?

There was 1 participant who died during this study from diabetes complications and an infection. At the time that this death happened, the study doctor thought it might be related to the study drug.

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

How many participants had adverse reactions?

There were 53.7% of participants who had adverse reactions during the study. This was 22 out of 41 participants.

- 71.4% of participants who took MEDI0382 had adverse reactions during the study. This was 15 out of 21 participants.
- 35.0% of participants who took the placebo had adverse reactions during the study. This was 7 out of 20 participants.

There were 7.3% of participants who stopped taking their study treatment because of adverse reactions they had during the study. This was 3 out of 41 patients.

- 9.5% of participants stopped taking MEDI0382 because of adverse reactions they had during the study. This was 2 out of 21 participants.
- 5.0% of participants stopped taking the placebo because of adverse reactions they had during the study. This was 1 out of 20 participants.

What adverse reactions did the participants have?

The most common adverse reactions were nausea and vomiting.

The table below shows the most common adverse reactions that happened in 3 or more participants during the study. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions during the study

	MEDI0382 (out of 21 participants)	Placebo (out of 20 participants)
Nausea	33.3% (7)	20.0% (4)
Vomiting	23.8% (5)	5.0% (1)
Diarrhoea	19.0% (4)	0.0% (0)
Indigestion	14.3% (3)	5.0% (1)
Low appetite	14.3% (3)	0.0% (0)
Low blood glucose (hypoglycaemia)	14.3% (3)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about using MEDI0382 in participants with T2DM and kidney problems.

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 **"NCT03550378"** into the **"Other Terms"** search box, and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2018-000019-26"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5670C00013"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 2a, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of MEDI0382 in Subjects with Type 2 Diabetes Mellitus and Renal Impairment

National Clinical Trials number: NCT03550378

AstraZeneca Protocol Number: D5670C00013

MedImmune Ltd, 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 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 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.

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