

**Research Sponsor:** MedImmune, Ltd.

**Drug Studied:** MEDI0382

**Study Title:** A study to learn how well MEDI0382 reaches the blood in people who already have kidney damage

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## ***Thank you!***

Thank you to the participants who took part in the clinical trial for the study drug MEDI0382. All of the participants helped researchers learn more about MEDI0382 to help people who already have kidney damage.

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. 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?**

The participants were in the study for up to about 8 weeks. But, the entire study took about 6 months to finish.

The study started in October 2017 and ended in April 2018. It included 37 participants in Germany and New Zealand.

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 people who already have kidney damage. 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 learn how well MEDI0382 reaches the blood in people who already have kidney damage. They also wanted to find out if the participants had any medical problems during the study.

The study drug, MEDI0382, is being developed to treat people with type 2 diabetes.

In people with type 2 diabetes, the body does not produce enough insulin. Insulin is made by the pancreas and controls the levels of sugar in the blood. If a person's blood sugar levels are too high or too low, he or she can develop several medical problems. One of the most common medical problems is damage to the kidneys.

MEDI0382 may be able to help control blood sugar levels in people with type 2 diabetes, which may be able to improve their health. But since many type 2 diabetes patients already have kidney damage, the researchers in this study wanted to learn if and how MEDI0382 affects the kidneys.

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

- Was there a difference in the amounts of MEDI0382 in the blood of participants with kidney damage compared to the blood of healthy participants?
- What medical problems did the participants have during the study?

To answer the questions in this study, researchers asked for the help of healthy men and women, as well as men and women with kidney damage. The participants in this study were between 44 to 82 years old at the start of the study.

## What kind of study was this?

**This was an “open-label” study.** This means the researchers and the participants knew what the participants were given.

All of the participants in the study got MEDI0382.

## What happened during the study?

**Before treatment,** the study doctors:

- did a physical examination
- took blood and urine samples
- checked the heart health of the participants using an electrocardiogram, also called an ECG
- checked the blood sugar levels of the participants
- checked the kidney health of the participants
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

**During treatment**, the participants were put into 1 of 5 treatment groups based on their kidney health:

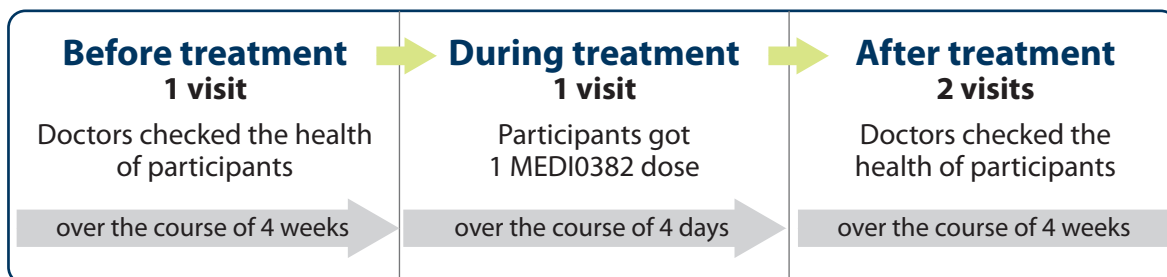
- Group 1, 2, 3, and 4 participants had different levels of kidney damage.
- Group 1 participants had the most kidney damage, and Group 4 participants had the least kidney damage.
- Group 5 participants were healthy.

All of the participants were given 1 dose of 100 micrograms, also called µg, of MEDI0382 through a needle under the skin.

Throughout the treatment period, the researchers continued checking the blood sugar levels, kidney health, and overall health of the participants and asking them how they were feeling.

**After treatment**, all of the participants visited their study site 2 more times. During these visits, the researchers checked the blood sugar levels, kidney health, and overall health of the participants 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 that each of the participants 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.

In this study, fewer Group 1 participants got treatment than the researchers had originally planned for. This happened because not enough of the participants who were scheduled to take part in Group 1 in the study actually completed the study. Because of this, the researchers decided there wasn't enough information from Group 1 to be included with the main results. So, some of the results in this summary are only for participants from Groups 2, 3, 4, and 5.

## Was there a difference in the amounts of MEDI0382 in the blood of participants with kidney damage compared to the blood of healthy participants?

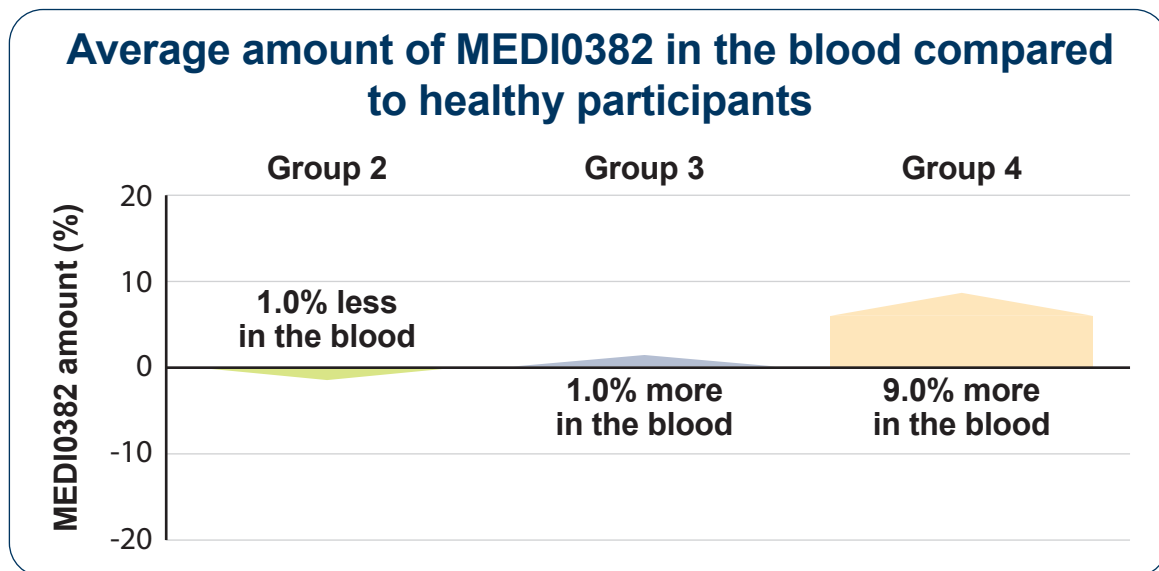
No. In general, the researchers found that the participants with kidney damage and the healthy participants had similar amounts of MEDI0382 in their blood. The researchers also found little difference in the amounts of MEDI0382 in the blood of the participants who had different levels of kidney damage.

To answer this question, the researchers measured the average and highest amounts of MEDI0382 in the blood 2 days after the participants got treatment. Then, the researchers compared these amounts for Groups 2, 3, and 4 with the amounts for the healthy participants. The researchers studied these amounts because they wanted to learn how much MEDI0382 reaches the blood. These results could help future researchers decide what drug amounts to give to patients based on their kidney health.

For the average amount of MEDI0382 in the blood, the researchers found that:

- Group 2 participants had about 1.0% less MEDI0382 in the blood compared to the healthy participants.
- Group 3 participants had about 1.0% more MEDI0382 in the blood compared to the healthy participants.
- Group 4 participants had about 9.0% more MEDI0382 in the blood compared to the healthy participants.

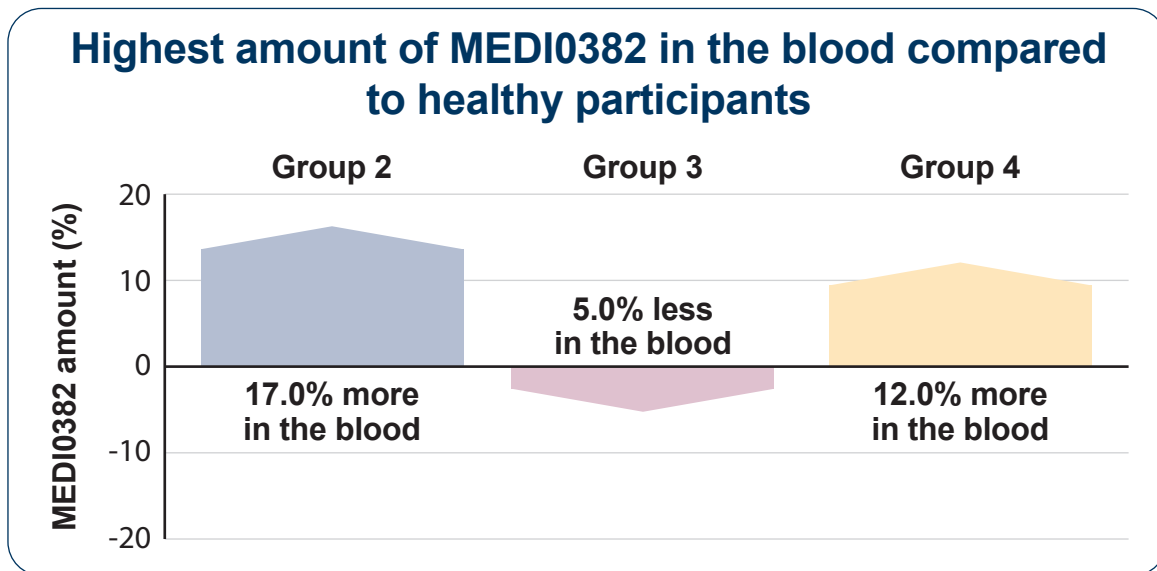
The figure below shows these results.



For the highest amount of MEDI0382 in the blood, the researchers found that:

- Group 2 participants had about 17.0% more MEDI0382 in the blood compared to the healthy participants.
- Group 3 participants had about 5.0% less MEDI0382 in the blood compared to the healthy participants.
- Group 4 participants had about 12.0% more MEDI0382 in the blood compared to the healthy participants.

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 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?

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 54.1% of participants who had adverse reactions during the study. This was 20 out of 37 participants.

None of the participants stopped taking MEDI0382 because of an adverse reaction they had during the study.

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

Adverse reactions during the study					
	Group 1 (out of 3 participants)	Group 2 (out of 8 participants)	Group 3 (out of 11 participants)	Group 4 (out of 7 participants)	Healthy participants (out of 8 participants)
How many participants had adverse reactions during the study?	33.3% (1)	50.0% (4)	72.7% (8)	42.9% (3)	50.0% (4)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment because of adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

## What adverse reactions did the participants have?

The most common adverse reaction was vomiting. The table below shows the adverse reactions that happened during the study.

Adverse reactions					
	Group 1 (out of 3 participants)	Group 2 (out of 8 participants)	Group 3 (out of 11 participants)	Group 4 (out of 7 participants)	Healthy participants (out of 8 participants)
Vomiting	33.3% (1)	50.0% (4)	18.2% (2)	42.9% (3)	37.5% (3)
Nausea	33.3% (1)	37.5% (3)	27.3% (3)	28.6% (2)	37.5% (3)
Headache	33.3% (1)	25.0% (2)	9.1% (1)	0.0% (0)	25.0% (2)
Rapid heartbeat	0.0% (0)	12.5% (1)	9.1% (1)	0.0% (0)	0.0% (0)
Decreased appetite	0.0% (0)	0.0% (0)	18.2% (2)	0.0% (0)	0.0% (0)
Bloating	0.0% (0)	0.0% (0)	9.1% (1)	0.0% (0)	12.5% (1)
Dizziness	33.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Diarrhea	0.0% (0)	0.0% (0)	9.1% (1)	0.0% (0)	0.0% (0)
Irregular heartbeat	0.0% (0)	0.0% (0)	9.1% (1)	0.0% (0)	0.0% (0)
Low blood sugar	0.0% (0)	0.0% (0)	9.1% (1)	0.0% (0)	0.0% (0)
Passing gas	0.0% (0)	0.0% (0)	9.1% (1)	0.0% (0)	0.0% (0)
Bruising at injection site	0.0% (0)	0.0% (0)	0.0% (0)	14.3% (1)	0.0% (0)
Reddening of the skin at injection site	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	12.5% (1)
Swelling in the digestive system	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	12.5% (1)

## How has this study helped participants and researchers?

This study helped researchers learn more about how well MEDI0382 reaches the blood in people who already have kidney damage.

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 “**NCT03235375**” into the “**Other Terms**” search box and click “**Search**”.
- [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type “**D5670C00008**” into the search box, and click “**Find a Study**”.

**Full study title:** A Phase 1, Open-Label, Single Dose, Parallel-Group Study to Evaluate the Pharmacokinetics, Safety and Tolerability of MEDI0382 in Subjects with Renal Impairment

**MedImmune Protocol number:** D5670C00008

MedImmune, Ltd., a member of the AstraZeneca Group, sponsored this study and has its headquarters at 1 Medimmune Way, Gaithersburg, MD 20878.

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 participants.



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.

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