Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, Ltd.

Drug Studied: MEDI0382

Study Title: A study to learn how 2 different forms of MEDI0382 act in the blood and if these forms are safe to take

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI0382. MedImmune, Ltd. 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.

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 study started in November 2017 and ended in January 2018. The study included 24 participants in the United States.

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

Different forms of the study drug, MEDI0382, are being developed to treat people with type 2 diabetes. In this study, the researchers wanted to compare how 2 of these forms acted in the blood in healthy participants. They also wanted to find out if the participants had any medical problems during the study.

In people with type 2 diabetes, a hormone known as insulin does not work as well as it should. Insulin is made by the pancreas and controls the levels of sugar in the blood. If someone's blood sugar levels are too high or too low, he or she can have medical problems. MEDI0382 was developed to help control blood sugar levels in people with type 2 diabetes, which could help reduce their medical problems.

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

- Did the 2 forms of MEDI0382 act in a similar way in the participants' blood?
- What medical problems did the participants have during the study from the 2 forms of MEDI0382?

The answers to these questions are important to know before other studies can be done that help find out if the 2 forms of MEDI0382 improve the health of people with type 2 diabetes.

The researchers asked for the help of healthy men and women. Everyone in the study was between 20 and 41 years old when they joined the study.

What kind of study was this?

This was an "open-label" study. This means that the researchers and the participants knew what drug the participants got during the study.

All of the participants got both forms of MEDI0382, but in a different order. The participants got both forms in an injection. The forms that were given in this study were called Form 2 and Form 3. Researchers have developed another form of MEDI0382, called Form 1, but that form was not used in this study.

Form 2 had been given to healthy participants and participants with type 2 diabetes in earlier studies with MEDI0382. This form was developed to be given in a single injection.

Form 3 had never been given to any participants. This form was developed to be given in multiple injections.

A computer program was used to randomly choose the order in which the participants got the 2 study treatments. 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 getting MEDI0382, the participants visited their study site 1 time. At this visit, the study doctors did certain tests to make sure the participants could join the study.

Then, the participants got MEDI0382. During treatment, the participants visited their study site 2 times. They got a different form of MEDI0382 at each of these visits.

After the first treatment visit, the participants waited 1 week before taking the next form. During this week, the study doctors asked the participants not to take certain medicines. This was done so that all of the MEDI0382 and any other medicines could leave the participants' bodies before they got their second injection.

After the 1 week, the participants visited their study site 1 more time and got the other form of MEDI0382.

Throughout the study, the study doctors checked the participants' overall health and blood sugar levels and asked them how they were feeling.

At the end of the study, the participants visited their study site 1 more time. During this visit, the study doctors checked the participants' overall health and blood sugar levels again and asked them how they were feeling.

What were the results of the study?

This is a summary of the main results from this study overall. The results each of the participants 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 the safest to take. 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.

There was 1 participant who left the study before taking a second treatment. Because of this, some of the results below include only 23 of the 24 participants. The participant left the study because of a medical problem that the researchers did not think was related to MEDI0382.

Did the 2 forms of MEDI0382 act in a similar way in the participants' blood?

No. The average amount of the 2 forms of MEDI0382 in the participants' blood was considered to be similar. The highest amount of the 2 forms of MEDI0382 in the blood was not considered to be similar. Both the average and highest amounts of MEDI0382 were higher when the participants took Form 3. But, the difference between the average amounts was considered to be too small for the researchers to consider this difference to be meaningful.

To answer this question, the researchers compared these averages by using a ratio. A ratio is a calculation that is used to compare 2 drug amounts to one another. In clinical studies, if the ratio between 2 amounts of a drug in the blood are:

- between 80% and 125%, the amounts are considered to be similar
- lower than 80% or higher than 125%, the amounts are not considered to be similar

The amounts of MEDI0382 in the blood were measured 2 days after the participants got each form.

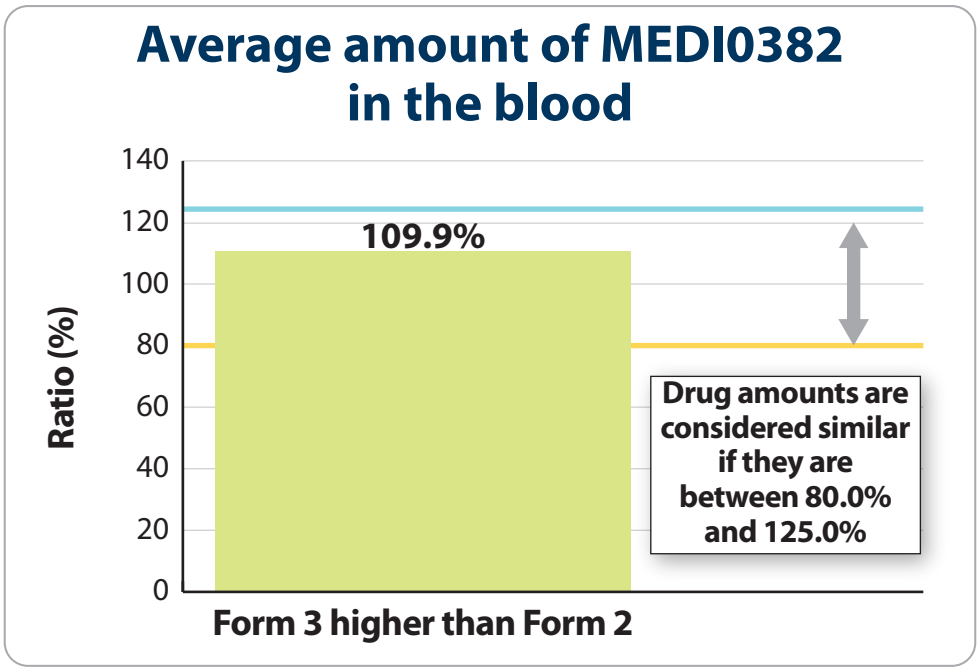
Average amount of MEDI0382 in the blood

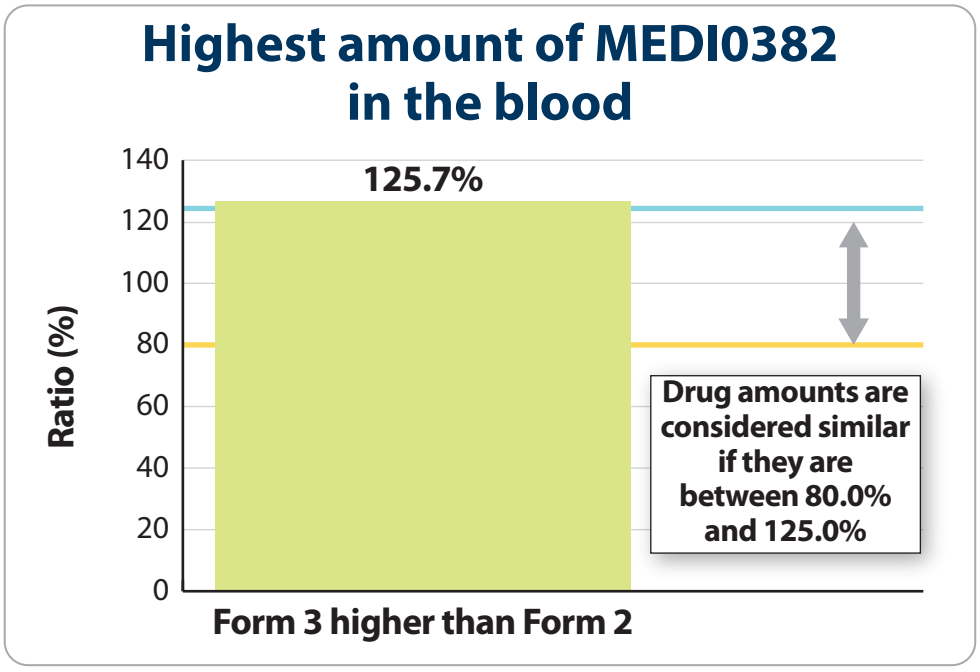
- The ratio between Form 3 and Form 2 was 109.9%. This means there was about 10% more MEDI0382 in the blood when the participants got Form 3 compared to when they got Form 2.
- The researchers considered these amounts to be similar.

Highest amount of MEDI0382 in the blood

- The ratio between Form 3 and Form 2 was 125.7%. This means there was about 26% more MEDI0382 in the blood when the participants got Form 3 compared to when they got Form 2.
- The researchers did not consider these amounts to be similar.

The figures below show these results.





What medical problems did the participants have during the study from the 2 forms of MEDI0382?

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.

There was 1 participant who left the study before taking a second treatment. Because of this, some of the results below include only 23 of the 24 participants. The participant left the study because of a medical problem that the researchers did not think was related to the study drug.

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 50.0% of participants who had adverse reactions after getting Form 2. This was 12 out of 24 participants.

There were 73.9% of participants who had adverse reactions after getting Form 3. This was 17 out of 23 participants.

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

What adverse reactions did the participants have?

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

Adverse reactions		
	Form 2 (out of 24 participants)	**Form 3 (out of 23 participants)**
Nausea	33.3% (8)	69.6% (16)
Vomiting	33.3% (8)	39.1% (9)
Headache	8.3% (2)	13.0% (3)
Dizziness	4.2% (1)	8.7% (2)
Decreased appetite	4.2% (1)	0.0% (0)
Blurred vision	0.0% (0)	4.3% (1)
Indigestion	0.0% (0)	4.3% (1)

How has this study helped patients and researchers?

This study helped researchers learn how 2 different forms of MEDI0382 act in the blood, and if these forms are safe to take.

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 **"NCT03341013"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5670C00003"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 1, Randomized, Cross-over, Two-period Pilot Study Investigating Bioequivalence Between a Single Dose of Formulation 2 and Formulation 3 of MEDI0382 in Healthy Adult Subjects

AstraZeneca Protocol Number: D5670C00003

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 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 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

www.ciscrp.org