MedImmune

A member of the AstraZeneca Group

Clinical Study Results

Research Sponsor: MedImmune LLC, a wholly owned subsidiary of AstraZeneca

Drug Studied: MEDI7219

Study Purpose: This study was done to learn about the safety of different doses and formulations of MEDI7219 in healthy participants

Protocol Number: D8170C00001

Thank you

Thank you for taking part in the clinical study for the study drug MEDI7219. 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 this study?

The researchers asked for the help of healthy men and women. This study happened in 6 parts: Part A to Part F. This summary shows only the results for Part B and Part C. The results for the remaining parts are in different summaries. They can be found online at www.trialsummaries.com if you enter the protocol number stated above.

The participants in Parts B and C of the study were 20 to 55 years of age when they joined.

These parts of the study included 36 participants in the United Kingdom.

Why was the research needed?

Researchers are looking for a better way to treat type 2 diabetes mellitus, also called T2DM. Before a drug can be approved for people to get, researchers do clinical studies to find out how safe it is and how it works.

In people with T2DM, the body does not make enough insulin and does not respond to insulin in the way that it should. Insulin is a hormone that controls the level of blood sugar. T2DM causes blood sugar levels to rise to levels that are higher than normal. This can cause medical problems.

The study drug, MEDI7219, is being developed to treat T2DM. It works by increasing the release of insulin into the blood after eating and helps to decrease blood sugar levels in people with T2DM.

Drugs of the same type as MEDI7219 are usually given through a needle into the skin. In Part B and Part C of the study, the researchers wanted to learn about the safety of MEDI7219 when it is given through a needle into a vein, also called an IV infusion, and when it is taken as a tablet by mouth. For the tablets, the researchers combined MEDI7219 with substances that help protect the tablet from stomach acid, and with substances that help it get into the blood. The combination of the study drug with other substances is called a formulation.

In these parts of the study, the researchers wanted to find out about the safety of different doses and formulations of MEDI7219. They wanted to study these when taken by mouth or given as an IV infusion in healthy participants.

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 MEDI7219 helps improve the health of people with T2DM.

What treatments did the participants get?

The participants in Part B and Part C of the study got MEDI7219 either as tablets by mouth or as an IV infusion.

Part B and Part C were "open-label" parts of the study. This means the participants, researchers, study doctors, and other study staff knew what each participant was getting.

In Part B, there were 2 treatment groups. In each treatment group, the participants took 2 different formulations of MEDI7219. In between taking each formulation, the participants waited at least 1 week. Overall, there were 4 separate formulations of MEDI7219 and each participant took 2 of them.

The chart below shows the treatments the researchers studied in Part B.

	MEDI7219 (26 participants)
	• Group 1: 12 participants took 2 formulations of MEDI7219. The second formulation was at the same dose as the first formulation • Group 2: 14 participants took 2 different formulations of MEDI7219. The second formulation was at a different dose than the first formulation.
	• Group 1: 2 tablets by mouth, then 2 tablets again after at least 1 week • Group 2: 1 tablet by mouth, then a second tablet after at least 1 week

In Part C, the participants got 1 of 2 different doses of MEDI7219 as an IV infusion.

The chart below shows the treatments the researchers studied in Part C.

	MEDI7219 (10 participants)
	• 1 of 2 different doses of MEDI7219
	• An IV infusion over 20 minutes

What happened during this study?

The study started in December 2017 and ended in May 2020. Additional treatment groups that were planned to be enrolled in the study were no longer enrolled because the sponsor decided to stop clinical studies for MEDI7219. This decision was not related to concerns over safety.

The participants in Part B were in the study for about 3 months. The participants in Part C were in the study for about 2 months.

Before the participants took study treatment, they visited their study site 1 time over a period of 4 weeks. At this visit, the study doctors made sure that the participants could join the study. They also:

- did a physical exam and asked about the participants' medical histories, their 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
- did breath tests

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

While the participants took study treatment in Part B, they had 2 stays at the study site for 4 days each. They took the study treatment on the second day of each stay. There was at least 1 week between stays. During this break where they were not taking treatment, the participants visited the study site 2 times.

While the participants got study treatment in Part C, they stayed at the study site for 4 days. The participants got the study treatment on the second day.

After the participants took study treatment in Part B, they visited their study site 3 times over a period of 1 month. At all of these visits, the study doctors checked the health of the participants.

After the participants got study treatment in Part C, they visited their study site 3 times over a period of 1 month. At these visits, the study doctors checked the health of the participants.

What were the results of this study?

This is a summary of the main results from Parts B and C of 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 changes.

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 throughout Parts B and C of the study. The study doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also 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 treatments.

Later in this document, there will be a summary of the adverse events that the study doctors thought might be related to the study treatments. This section is a summary of all the adverse events, whether they might be related to the study treatments 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.

	MEDI7219 in Part B (out of 26 participants)	**MEDI7219 in Part C** (out of 10 participants)
How many participants had adverse events?	80.8% (21)	100.0% (10)
How many participants had serious adverse events?	0.0% (0)	0.0% (0)
How many participants stopped taking study treatment because of adverse events?	7.7% (2)	Not applicable as the participants got only 1 dose of MEDI7219

The most common adverse events in Part B were:

- Nausea
- Vomiting
- Decreased appetite
- Headache
- Back pain
- Dizziness

The most common adverse events in Part C were:

- Nausea
- Vomiting
- Headache
- Stomach discomfort
- Back pain

What medical problems happened during this study?

This section is a summary of the medical problems the participants had during Parts B and C of the study that the study doctors thought might be related to the study treatments. 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 treatments. A lot of research is needed to know whether a treatment causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for MEDI7219.

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.

Did any adverse reactions happen during Parts B and C?

	MEDI7219 in Part B (out of 26 participants)	**MEDI7219 in Part C** (out of 10 participants)
How many participants had adverse reactions?	76.9% (20)	100.0% (10)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)
How many participants stopped taking study treatment because of adverse reactions?	7.7% (2)	Not applicable as the participants got only 1 dose of MEDI7219

What serious adverse reactions happened during Parts B and C?

None of the participants had serious adverse reactions during Part B or C.

What adverse reactions happened during Parts B and C?

The most common adverse reaction during Part B and Part C of the study was nausea.

The table below shows the most common adverse reactions that happened in 3 or more of the participants during Part B of the study. There were other adverse reactions in Part B, but these happened in fewer participants. Some participants may have had more than 1 adverse reaction.

Most common adverse reactions in Part B

Adverse reaction	**MEDI7219** (out of 26 participants)
Nausea	61.5% (16)
Decreased appetite	38.5% (10)
Vomiting	38.5% (10)
Headache	15.4% (4)

The table below shows all of the adverse reactions that happened during Part C of the study.

Adverse reactions in Part C

Adverse reaction	**MEDI7219** (out of 10 participants)
Nausea	90.0% (9)
Decreased appetite	30.0% (3)
Vomiting	30.0% (3)
Headache	20.0% (2)

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of MEDI7219 in healthy participants.

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 MEDI7219 are not 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 **"NCT03362593"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D8170C00001"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase 1 Single and Multiple Ascending Dose Study to Evaluate the Safety, Tolerability and Pharmacokinetics of MEDI7219 in Healthy Subjects, including Assessment of the Impact of Changes to the Oral Formulation and Determination of Intravenous Pharmacokinetics

AstraZeneca Protocol Number: D8170C00001

National Clinical Trials Number: NCT03362593

MedImmune, LLC sponsored this study and has its headquarters in Gaithersburg, MD, USA.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you

Clinical study participants and their families 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

Version 1.0 2021_08_31