Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, Ltd.

Drug Studied: MEDI4920

Study Title: A study to learn about the safety of MEDI4920 in participants with rheumatoid arthritis

Thank you!

Thank you to the participants who took part in the clinical study for the study drug MEDI4920. 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 June 2016 and ended in September 2018. The study included 57 participants in Poland and 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 who have rheumatoid arthritis, also called RA. 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 people who have RA, the immune system can attack the body's own tissues, joints, and organs. This can lead to pain and swelling in the body. There are treatments that help the symptoms of RA, but sometimes the symptoms come back or do not completely go away.

The study drug, MEDI4920, is being developed to treat patients who have RA. In this study, the researchers wanted to learn more about the safety of MEDI4920 in participants who have RA.

The main question the researchers wanted to answer in this study was:

- What medical problems did the participants have during the study?

The answer to this question is important to know before other studies can be done that help find out if MEDI4920 improves the health of people who have RA.

The researchers asked for the help of men and women who have RA. The participants in the study were 31 to 70 years old when they joined the study.

What kind of study was this?

This was a “double blind” study. This means none of the participants or researchers knew which treatment the participants 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 each participant got so they could create a report of the study results.

The participants in this study got MEDI4920 or a placebo. 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.

MEDI4920 and the placebo were given through a needle into the blood. This is known as intravenous treatment, also called IV treatment.

The doses of MEDI4920 were measured in milligrams, also called mg.

This was also a “dose escalation” study. This means that the participants who got MEDI4920 started out getting a low dose. The study doctors carefully looked at the results for these participants. Then, the researchers decided whether to increase the dose in the next group of participants. Each participant who got MEDI4920 got only 1 dose amount during the study. Researchers use dose escalation studies to learn about the safety of a specific dose before participants are given a higher dose.

A computer program was used to randomly choose the group that each participant was in. 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 study treatment, the participants visited their study site 1 time. At this visit, the study doctors checked the participants' RA symptoms and did tests to make sure they could join the study. This visit happened within about 1 month of the treatment groups being chosen.

During the treatment period, the participants visited their study site 9 times over the course of about 3 months. There were 5 different treatment groups.

The table below shows the treatments the participants got.

		
Group 1 (8 participants)	75 mg of MEDI4920	All 57 participants got their study treatment: • through an IV • once every 2 weeks for up to about 3 months
Group 2 (10 participants)	500 mg of MEDI4920	
Group 3 (12 participants)	1,000 mg of MEDI4920	
Group 4 (12 participants)	1,500 mg of MEDI4920	
Group 5 (15 participants)	Placebo	

Throughout the treatment period, the study doctors checked the participants' RA symptoms and overall health and asked them how they were feeling.

At the end of the study, the participants visited their study site 5 more times over the course of about 3 months. During these visits, the study doctors checked the participants' RA symptoms and overall health 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 participant had might be different and are not in this summary.

The websites listed at the end of this summary may have a full report of the study results.

What medical problems did the participants have during the study?

To answer this question, the researchers recorded any medical problems the participants had during the study. These medical problems are called "adverse events". An adverse event is any medical problem that happens during the study. An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care. Adverse events may or may not be caused by the study drug.

How many participants had serious adverse events?

There were 2.4% of participants who got MEDI4920 who had serious adverse events during the study. This was 1 out of 42 participants. This serious adverse event was swelling in the brain. The study doctors did not think this serious adverse event was related to the study treatment.

None of the participants who got the placebo had serious adverse events during the study.

None of the participants died due to serious adverse events during the study.

The websites listed at the end of this summary may have other information about adverse events that happened during this study.

How many participants had adverse events?

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

Adverse events during the study

	75 mg MEDI4920 (out of 8 participants)	500 mg MEDI4920 (out of 10 participants)	1,000 mg MEDI4920 (out of 12 participants)	1,500 mg MEDI4920 (out of 12 participants)	Placebo (out of 15 participants)
How many participants had adverse events during the study?	37.5% (3)	70.0% (7)	50.0% (6)	83.3% (10)	86.7% (13)
How many participants had serious adverse events during the study?	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)	0.0% (0)
How many participants stopped treatment because of adverse events?	12.5% (1)	0.0% (0)	0.0% (0)	8.3% (1)	0.0% (0)

What adverse events did the participants have?

The most common adverse event was an infection of the nose, throat, and airways. The table below shows the adverse events that happened in at least 3 participants during the study. There were other adverse events, but they happened in fewer participants.

Most common adverse events

	75 mg MEDI4920 (out of 8 participants)	500 mg MEDI4920 (out of 10 participants)	1,000 mg MEDI4920 (out of 12 participants)	1,500 mg MEDI4920 (out of 12 participants)	Placebo (out of 15 participants)
Infection of the nose, throat, and airways	0.0% (0)	10.0% (1)	16.7% (2)	0.0% (0)	26.7% (4)
Diarrhea	25.0% (2)	10.0% (1)	0.0% (0)	0.0% (0)	6.7% (1)
Common cold	0.0% (0)	20.0% (2)	0.0% (0)	0.0% (0)	6.7% (1)
Headache	0.0% (0)	10.0% (1)	0.0% (0)	0.0% (0)	13.3% (2)
Increase in amount of alanine aminotransferase in the blood (a sign of liver damage)	0.0% (0)	0.0% (0)	8.3% (1)	16.7% (2)	0.0% (0)
Feeling tired	0.0% (0)	0.0% (0)	8.3% (1)	0.0% (0)	13.3% (2)
Increased sweating	0.0% (0)	0.0% (0)	0.0% (0)	25.0% (3)	0.0% (0)
Urinary tract infection	0.0% (0)	0.0% (0)	0.0% (0)	25.0% (3)	0.0% (0)
Sinus infection	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)	13.3% (2)

What adverse reactions did the participants have during the study?

This section is a summary of the adverse reactions 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 that happened during this study.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

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

Adverse reactions during the study

	75 mg MEDI4920 (out of 8 participants)	500 mg MEDI4920 (out of 10 participants)	1,000 mg MEDI4920 (out of 12 participants)	1,500 mg MEDI4920 (out of 12 participants)	Placebo (out of 15 participants)
How many participants had adverse events during the study?	12.5% (1)	50.0% (5)	25.0% (3)	50.0% (6)	33.3% (5)
How many participants had serious adverse events 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 events?	12.5% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions did the participants have?

The most common adverse reactions were an infection of the nose, throat, and airways and increased sweating. The table below shows the adverse reactions that happened in at least 2 participants during the study. There were other adverse reactions, but they happened in fewer participants.

Most common adverse reactions					
	75 mg MEDI4920 (out of 8 participants)	**500 mg MEDI4920 (out of 10 participants)**	**1,000 mg MEDI4920 (out of 12 participants)**	**1,500 mg MEDI4920 (out of 12 participants)**	**Placebo (out of 15 participants)**
Infection of the nose, throat, and airways	0.0% (0)	10.0% (1)	0.0% (0)	0.0% (0)	13.3% (2)
Increased sweating	0.0% (0)	0.0% (0)	0.0% (0)	25.0% (3)	0.0% (0)
Diarrhea	12.5% (1)	10.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Herpes of the mouth	0.0% (0)	10.0% (1)	8.3% (1)	0.0% (0)	0.0% (0)
Feeling hot	0.0% (0)	10.0% (1)	0.0% (0)	0.0% (0)	6.7% (1)
Feeling tired	0.0% (0)	0.0% (0)	8.3% (1)	0.0% (0)	6.7% (1)
Decrease in amount of white blood cells (this can lead to increased risk of infection)	0.0% (0)	0.0% (0)	0.0% (0)	16.7% (2)	0.0% (0)
Sinus infection	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)	6.7% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of MEDI4920 in patients who have RA.

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 MEDI4920 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 **"NCT02780388"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5100C00002"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 1b Randomized, Double-blind, Placebo-controlled Multiple-ascending Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, Immunogenicity, Pharmacodynamics, and Clinical Response of MEDI4920 in Subjects with Adult-onset Rheumatoid Arthritis

AstraZeneca Protocol Number: D5100C00002

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.

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