Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune

Treatment Studied: MEDI3506

Study Title: A study to learn about the safety and tolerability of MEDI3506 in healthy participants, in participants with chronic obstructive pulmonary disease, and in healthy Japanese participants

Thank you

Thank you to the participants who took part in the clinical study for the study treatment MEDI3506. MedImmune sponsored this study and thinks it is important to share the results of the study. 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 study doctor or staff at your study site.

Who took part in this study?

There were 3 parts to this study. The researchers asked for the help of different participants for each part.

- **Part 1** included men and women who had mild allergies. These participants were 23 to 55 years old when they joined the study.
- **Part 2** included men and women who had chronic obstructive pulmonary disease, also called COPD. These participants were 55 to 71 years old when they joined the study.
- **Part 3** included healthy Japanese men. These participants were 25 to 48 years old when they joined the study.

Overall, the study included a total of 88 participants in 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 chronic obstructive pulmonary disease, also called COPD. Before a treatment can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

COPD is a long-term condition caused by damage to and narrowing of the airways. COPD can lead to symptoms such as difficulty breathing, coughing, and phlegm.

There are treatments that help people manage their COPD symptoms. But, these treatments may not work for some people. They may also cause medical problems for some people.

COPD symptoms can happen when a protein in the body causes swelling in the airways. The study treatment, MEDI3506, was designed to stop swelling by blocking this protein from sending signals to the body. MEDI3506 is being developed to treat COPD, asthma, and eczema. Asthma is a condition that causes the airways to narrow, swell, and create extra mucus. This can cause symptoms such as wheezing, coughing, and difficulty breathing. Eczema is a condition in which the skin becomes itchy and red.

In this study, the researchers wanted to learn about the safety of different doses and dosing schedules of MEDI3506. They wanted to learn how MEDI3506 affects participants who have mild allergies, participants who have COPD, and healthy Japanese participants. This information may help researchers determine what doses of MEDI3506 to use with future study participants, and if ethnicity plays a role in the effects of MEDI3506.

What was the purpose of this study?

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

- What signs and symptoms did the participants have during the study?
- What medical problems happened during the study?

The answers to these questions are important to know before other studies can be done to find out if MEDI3506 improves the health of people who have COPD, asthma, or eczema.

What treatments did the participants get?

The participants in this study got MEDI3506 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.

The participants got study treatment in 1 of 2 ways. They could get it through a needle under the skin, also called an injection under the skin. They could also get it through a needle into a vein. This is known as intravenous treatment, also called IV treatment. Since IV treatment goes directly into a vein, it reaches the blood faster and is transported faster throughout the body compared to an injection.

This was a “blinded” study. This means the participants, researchers, study doctors, and other study staff did not know what treatment each participant was getting within each part, but the research sponsor knew. 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 researchers found out which treatment the participants got so they could create a report of the study results.

Part 1

In Part 1, there were 8 groups of participants. Each group got MEDI3506 or the placebo through an injection under the skin or through IV treatment. This part was done as a “dose escalation” part. This means that for the participants who got MEDI3506, the first group of participants started out taking a low dose. The study doctors looked at the results for these participants. Then, the researchers decided whether or not to increase the dose of MEDI3506 in the next group of participants.

After the researchers studied the safety results from Part 1, the participants in Part 2 and Part 3 could start getting study treatment.

Part 2

In Part 2, there were 4 groups of participants. Each group got either MEDI3506 or the placebo through injections under the skin.

Part 2 was also a “dose escalation” part. This means that for the participants who got MEDI3506, the first group of participants started out taking a low dose. The study doctors looked at the results for these participants. Then, the researchers decided whether or not to increase the dose of MEDI3506 in the next group of participants.

Part 3

In Part 3, there were 2 groups of participants. These participants got either MEDI3506 or the placebo through IV treatment.

Within each group, a computer program was used to randomly choose the treatment each participant got. This helps make sure the treatments are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

The chart below shows the treatments the participants got.

	Part 1 Participants had mild allergies (56 participants)	**Part 2 Participants had COPD (24 participants)**	**Part 3 Participants were healthy Japanese men (8 participants)**
How was the treatment given? 	Injection under the skin or IV	Injection under the skin	IV
What treatments were the participants given? 	• 42 participants were given 1 of 7 MEDI3506 doses • 14 participants were given the placebo	• 18 participants were given MEDI3506 • 6 participants were given the placebo	• 6 participants were given MEDI3506 • 2 participants were given the placebo
How many times were participants given treatment? 	Once	3 times over the course of about 4 weeks	Once

What happened during this study?

The study started in May 2017 and ended in September 2019.

Before the participants in any part got treatment, they visited their study site 1 time. At this visit, the study doctors checked to make sure the participants could join the study. The study doctors:

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

Throughout all 3 parts, the study doctors continued doing these tests and measurements.

In Part 1, the participants stayed at their study site for about 1 week and got 1 dose of MEDI3506 or the placebo.

After this, the participants visited their study site 11 times over the course of about 6 months so the study doctors could check their health.

In Part 2, the participants visited their study site 6 times over the course of about 4 weeks. At 3 of those visits, they got MEDI3506 or the placebo. At the other 3 visits, the study doctors only checked the health of the participants.

After this, the participants visited their study site 8 times over the course of about 5 months so the study doctors could check their health.

In Part 3, the participants stayed at their study site for about 1 week and got 1 dose of MEDI3506 or the placebo.

After this, the participants visited their study site 9 times over the course of about 6 months so the study doctors could check their health.

What were the results of this 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.

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 more information about the study results.

What signs and symptoms did the participants have during the study?

To answer this question, the study doctors recorded the results of the participants' tests and measurements that were done throughout the study. The researchers looked at the results for each part of the study.

Overall, the researchers found that there were some changes in the results of these tests and measurements. But, they did not consider these changes to be meaningful.

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 or not they might be related to the study treatments. 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.

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

Adverse events during this study	Part 1 Participants had mild allergies (56 participants)		Part 2 Participants had COPD (24 participants)		Part 3 Participants were healthy Japanese men (8 participants)	
	MEDI3506 (out of 42 participants)	Placebo (out of 14 participants)	MEDI3506 (out of 18 participants)	Placebo (out of 6 participants)	MEDI3506 (out of 6 participants)	Placebo (out of 2 participants)
How many participants had adverse events?	88.1% (37)	71.4% (10)	94.4% (17)	83.3% (5)	83.3% (5)	100.0% (2)
How many participants had serious adverse events?	0.0% (0)	0.0% (0)	16.7% (3)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants left this study due to adverse events?	0.0% (0)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
What was the most common adverse event?	Common cold		Runny nose		Feeling tired	

Deaths due to serious adverse events happened only in Part 2 of the study.

In Part 2, 11.1% of participants who got MEDI3506 died. This was 2 out of 18 participants:

- 1 participant who got MEDI3506 died of a heart attack.
- 1 participant who got MEDI3506 died of lung cancer.

The study doctors did not think these deaths were related to MEDI3506. Both events happened sometime after the last dose of MEDI3506 was given. Both participants were current or former smokers, which are known risk factors for heart attack and lung cancer.

None of the participants who got the placebo in Part 2 died.

Before the study started, the researchers thought that MEDI3506 might cause specific types of adverse events. The researchers wanted to learn if the participants getting MEDI3506 in this study had these specific types of adverse events. These adverse events are known as "adverse events of special interest", also called AESIs.

The table below shows how many participants had AESIs during this study.

AESIs during this study	Part 1 Participants had mild allergies (56 participants)		Part 2 Participants had COPD (24 participants)		Part 3 Participants were healthy Japanese men (8 participants)	
	MEDI3506 (out of 42 participants)	Placebo (out of 14 participants)	MEDI3506 (out of 18 participants)	Placebo (out of 6 participants)	MEDI3506 (out of 6 participants)	Placebo (out of 2 participants)
How many participants had AESIs?	28.6% (12)	7.1% (1)	66.7% (12)	50.0% (3)	16.7% (1)	0.0% (0)

The table below and continued on the next page shows the AESIs that happened during this study.

AESIs during this study	Part 1 Participants had mild allergies (56 participants)		Part 2 Participants had COPD (24 participants)		Part 3 Participants were healthy Japanese men (8 participants)	
	MEDI3506 (out of 42 participants)	Placebo (out of 14 participants)	MEDI3506 (out of 18 participants)	Placebo (out of 6 participants)	MEDI3506 (out of 6 participants)	Placebo (out of 2 participants)
Reaction at the injection site	2.4% (1)	0.0% (0)	33.3% (6)	16.7% (1)	0.0% (0)	0.0% (0)
Feeling warm at the injection site	2.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Pain at the injection site	2.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Skin discomfort at the injection site	2.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

AESIs during this study (Continued)	**Part 1 Participants had mild allergies (56 participants)**		**Part 2 Participants had COPD (24 participants)**		**Part 3 Participants were healthy Japanese men (8 participants)**	
	MEDI3506 (out of 42 participants)	**Placebo (out of 14 participants)**	**MEDI3506 (out of 18 participants)**	**Placebo (out of 6 participants)**	**MEDI3506 (out of 6 participants)**	**Placebo (out of 2 participants)**
Skin redness at the injection site	2.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Food poisoning in the digestive system	7.1% (3)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Diarrhea	0.0% (0)	0.0% (0)	11.1% (2)	0.0% (0)	16.7% (1)	0.0% (0)
Discomfort in the stomach area	2.4% (1)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Pain in the stomach area	2.4% (1)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Dry heaving	2.4% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Indigestion	2.4% (1)	0.0% (0)	5.6% (1)	16.7% (1)	0.0% (0)	0.0% (0)
Nausea	0.0% (0)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Passing gas	0.0% (0)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Vomiting	2.4% (1)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Toothache	2.4% (1)	0.0% (0)	11.1% (2)	0.0% (0)	0.0% (0)	0.0% (0)
Discomfort in the mouth	2.4% (1)	7.1% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Pain in the gums	0.0% (0)	0.0% (0)	0.0% (0)	16.7% (1)	0.0% (0)	0.0% (0)
Worsening of COPD	0.0% (0)	0.0% (0)	16.7% (3)	0.0% (0)	0.0% (0)	0.0% (0)
Heart attack	0.0% (0)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Irregular heartbeat	0.0% (0)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)

What medical problems happened during the study?

This section is a summary of the adverse events the participants had during the study that the study doctors thought might be related to the study treatments. These adverse events 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 the treatments.

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 this study?

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

Adverse reactions during this study	Part 1 Participants had mild allergies (56 participants)		Part 2 Participants had COPD (24 participants)		Part 3 Participants were healthy Japanese men (8 participants)	
	MEDI3506 (out of 42 participants)	Placebo (out of 14 participants)	MEDI3506 (out of 18 participants)	Placebo (out of 6 participants)	MEDI3506 (out of 6 participants)	Placebo (out of 2 participants)
How many participants had adverse reactions?	26.2% (11)	7.1% (1)	33.6% (6)	16.7% (1)	16.7% (1)	50.0% (1)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants left this study due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

None of the participants in any of the parts died due to serious adverse reactions.

What adverse reactions happened during this study?

The table below shows the adverse reactions that happened in more than 1 participant in any part during this study. There were other adverse reactions that happened, but those happened in fewer participants.

Most common adverse reactions during this study

Adverse reactions during this study	Part 1 Participants had mild allergies (56 participants)		Part 2 Participants had COPD (24 participants)		Part 3 Participants were healthy Japanese men (8 participants)	
	MEDI3506 (out of 42 participants)	Placebo (out of 14 participants)	MEDI3506 (out of 18 participants)	Placebo (out of 6 participants)	MEDI3506 (out of 6 participants)	Placebo (out of 2 participants)
Reaction at the injection site	2.4% (1)	0.0% (0)	33.3% (6)	16.7% (1)	0.0% (0)	0.0% (0)
Headache	11.9% (5)	0.0% (0)	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Feeling tired	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	16.7% (1)	50.0% (1)

How has this study helped patients and researchers?

This study helped researchers learn about the safety and tolerability of MEDI3506 in participants with mild allergies, in participants with COPD, and in healthy Japanese 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 MEDI3506 are ongoing and 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 **"NCT03096795"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D9180C00001"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase 1, Randomised, Blinded, Placebo-controlled Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Immunogenicity of MEDI3506 Administered as Single Ascending Doses in Healthy Adult Subjects with a History of Mild Atopy, as Multiple Ascending Doses in Adult Subjects with Chronic Obstructive Pulmonary Disease and as a Single Dose in Healthy Japanese Subjects

AstraZeneca Protocol Number: D9180C00001

National Clinical Trials Number: NCT03096795

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

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 participants for clinical studies, nor is it involved in conducting clinical studies.

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