Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune

Drug Studied: MEDI3902

Study Title: A study to learn about using MEDI3902 in participants who are on breathing machines and are at risk of developing bacterial pneumonia

Thank you

Thank you to the participants who took part in the clinical study for the study drug MEDI3902, and to the participants' families. All of the participants helped researchers learn more about MEDI3902 and help people who are on breathing machines and are at risk of developing bacterial pneumonia.

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. We hope it helps the participants and their families understand and feel proud of their important role in medical research.

If you or a family member participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

Overview of this study

Why was the research needed?

Researchers are looking for a better way to treat bacterial pneumonia. Before a drug can be approved for people to take, researchers do clinical studies to find out how it works and how safe it is.

What treatments did the participants get?

The participants in this study got MEDI3902, or a placebo that looked like MEDI3902. 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.

What were the results of this study?

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

- **Did MEDI3902 affect the number of participants who developed bacterial pneumonia?**
  No. Overall, the researchers found that MEDI3902 did not affect the number of participants who developed bacterial pneumonia.

- **What signs and symptoms did the participants have during this study?**
  An adverse event is any sign or symptom that participants have during a study.
  There were 98.0% of participants who got MEDI3902 who had adverse events during the study.
  There were 97.6% of participants who got the placebo who had adverse events during the study.
  The most common of these adverse events was low blood pressure.

- **What medical problems happened during this study?**
  There were 3.0% of participants who got MEDI3902 who had medical problems during the study that the study doctors thought might be related to the study treatment.
  There were 1.2% of participants who got the placebo who had medical problems during the study that the study doctors thought might be related to the study treatment.
  The most common of these medical problems was a skin reaction at the infusion site. An infusion is when a treatment is given through a needle into a vein over a period of time.

More details about the results of this study are included later in this summary.

Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it can also be found on those websites.

Who took part in this study?

The researchers asked for the help of men and women who were already in the hospital and were on breathing machines. These participants were at risk of developing bacterial pneumonia. The participants were 22 to 89 years old when they joined.

The study included 188 participants in Austria, Belgium, Croatia, the Czech Republic, France, Greece, Hungary, Ireland, Israel, Portugal, Spain, Turkey, the United Kingdom, and the United States.

Why was the research needed?

Researchers are looking for a better way to treat bacterial pneumonia. Before a drug can be approved for people to take, researchers do clinical studies to find out how it works and how safe it is.

In this study, the researchers wanted to find out if MEDI3902 worked in participants who were at risk of developing bacterial pneumonia. They also wanted to find out if the participants had any medical problems during the study.

A common cause of pneumonia is breathing in harmful bacteria. These bacteria can cause lung damage and other medical problems, such as coughing, wheezing, and difficulty breathing.

Some people have a high risk of getting bacterial pneumonia and the medical problems it can cause. This includes people who are in the hospital and on machines to help them breathe.

There are treatments to prevent or treat bacterial pneumonia. But, these treatments may not work for some people, and they may cause medical problems. The study drug, MEDI3902, is being developed to help the body's immune system fight harmful bacteria that cause pneumonia.

In this study, the researchers wanted to learn if MEDI3902 helped stop the participants from developing bacterial pneumonia. The participants were already in the hospital and were on machines to help them breathe. These participants had harmful bacteria in their bodies before the study started, but they had not developed pneumonia.

What was the purpose of this study?

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

- Did MEDI3902 affect the number of participants who developed bacterial pneumonia?
- What signs and symptoms did the participants have during this study?
- What medical problems happened during this study?

The answers to these questions are important to know before other studies can be done to learn if MEDI3902 helps improve the health of those at risk of developing bacterial pneumonia.

What treatments did the participants get?

In this study, the participants got either MEDI3902 or a placebo through a needle into a vein over a period of time. This is known as an infusion. 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.

This was a "double-blind" study. This means none of the participants, researchers, study doctors, or other study staff knew what treatment each participant was getting. 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 the participants got so they could create a report of the study results.

A computer program was used to randomly choose the treatment each participant got. 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.

The doses of MEDI3902 were measured in milligrams, also called mg. The chart below shows the treatments the participants got. Of the 188 participants in this study, there were 4 participants who did not receive treatment. This was because they did not meet the study guidelines or the study doctors accidentally found out the treatment given to them. So, the below treatment groups show 184 of the 188 participants.

	500 mg MEDI3902 (16 participants)	1,500 mg MEDI3902 (85 participants)	Placebo (83 participants)
How did the participants get study treatment?	Through an infusion	Through an infusion	Through an infusion
How often did the participants get study treatment?	1 time	1 time	1 time

What happened during this study?

The participants were in this study for up to about 8 weeks. But, the entire study took over 3 years to finish. The study started in March 2016 and ended in December 2019.

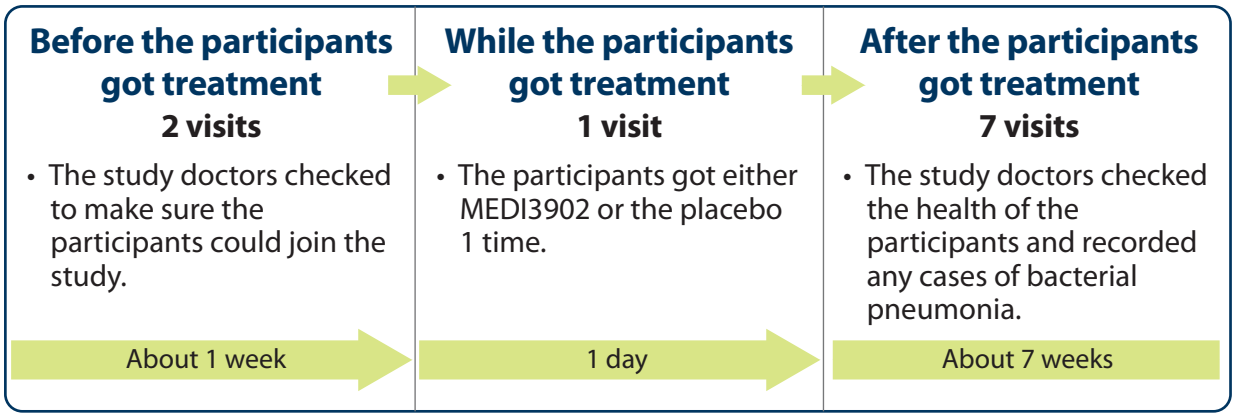
Before the participants got treatment, the study doctors visited them 2 times over the course of about 1 week. During this time, the study doctors checked to make sure the participants could join the study. The study doctors:

- did a physical examination and checked the participants' vital signs
- took blood samples
- checked to confirm that the participants had harmful bacteria in their body, but had not developed pneumonia
- asked the participants or their legal guardians about the participants' medical history, how they were feeling, and what medicines they were taking

Two days after the second visit, the study doctors visited the participants a third time. During this visit, the participants got their randomly chosen treatment.

After the participants got treatment, the study doctors visited the participants 7 times over the course of about 7 weeks. At these visits, the study doctors checked the participants' health, recorded any instances of bacterial pneumonia, and asked the participants how they were feeling.

The chart below shows how the study was done.



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. A full list of the questions the researchers wanted to answer can be found on the websites listed at the end of this summary. When 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.

Of the 188 participants in this study, there were 4 participants who did not receive treatment. This was because they did not meet the study guidelines or the study doctors accidentally found out the treatment given to them. So, the below results are for only 184 of the 188 participants.

Did MEDI3902 affect the number of participants who developed bacterial pneumonia?

No. Overall, the researchers found that there were differences in the percentage of participants who developed bacterial pneumonia among the treatment groups. But, the researchers did not consider these differences to be meaningful.

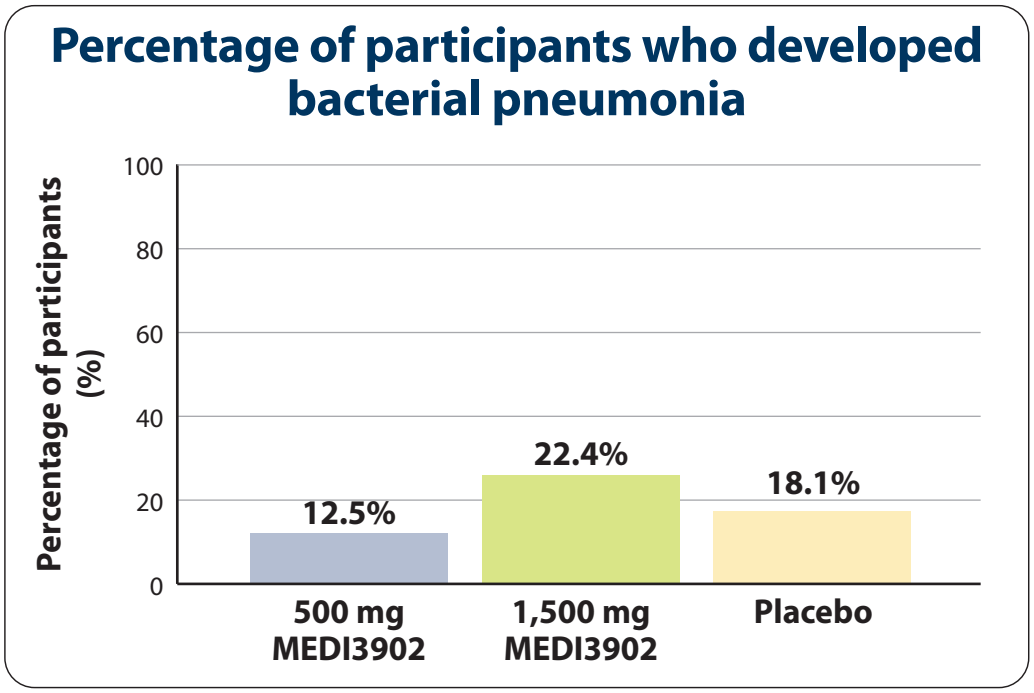
To answer this question, the researchers counted the number of participants in each treatment group who developed bacterial pneumonia within 3 weeks of getting treatment. Then, they calculated the percentage in each treatment group and compared the results.

Overall, the researchers found that the treatment group that got 1,500 mg of MEDI3902 had the highest percentage of participants who developed bacterial pneumonia. The researchers also found that the treatment group that got 500 mg of MEDI3902 had the lowest percentage of participants who developed bacterial pneumonia.

The researchers found that 3 weeks after treatment:

- 12.5% of participants who got 500 mg of MEDI3902 developed bacterial pneumonia. This was 2 out of 16 participants.
- 22.4% of participants who got 1,500 mg of MEDI3902 developed bacterial pneumonia. This was 19 out of 85 participants.
- 18.1% of participants who got the placebo developed bacterial pneumonia. This was 15 out of 83 participants.

The figure below shows these results.



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

To answer this question, the study doctors 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 treatment. 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.

Of the 188 participants in this study, there were 4 participants who did not receive treatment. This was because they did not meet the study guidelines or the study doctors accidentally found out the treatment given to them. So, the below results are for only 184 of the 188 participants.

In this study:

- 98.0% of participants who got MEDI3902 had adverse events.
- 97.6% of participants who got the placebo had adverse events.
- The most common adverse event was low blood pressure.
- The most common serious adverse event was a heart attack.

There were 26.7% of participants who got MEDI3902 who died due to adverse events during this study. This was 27 out of 101 participants. The study doctors did not think these deaths were related to MEDI3902.

There were 22.9% of participants who got the placebo who died due to adverse events during this study. This was 19 out of 83 participants.

The table below shows how many participants had adverse events.

Adverse events during this study

	500 mg MEDI3902 (16 participants)	1,500 mg MEDI3902 (85 participants)	Placebo (83 participants)
How many participants had adverse events?	93.8% (15)	98.8% (84)	97.6% (81)
How many participants had serious adverse events?	25.0% (4)	44.7% (38)	42.2% (35)
How many participants left this study due to adverse events?	0.0% (0)	0.0% (0)	0.0% (0)

What medical problems happened during this 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 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 the treatments.

Of the 188 participants in this study, there were 4 participants who did not receive treatment. This was because they did not meet the study guidelines or the study doctors accidentally found out the treatment given to them. So, the below results are for only 184 of the 188 participants.

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?

There were 3.0% of participants who got MEDI3902 who had adverse reactions during this study:

- None of the participants who got 500 mg of MEDI3902 had adverse reactions.
- 3.5% of participants who got 1,500 mg of MEDI3902 had adverse reactions. This was 3 out of 85 participants.

There were 1.2% of participants who got the placebo who had adverse reactions during the study. This was 1 out of 83 participants.

What serious adverse reactions happened during this study?

None of the participants who got MEDI3902 had serious adverse reactions during this study.

There were 1.2% of participants who got the placebo who had serious adverse reactions during this study. This was 1 out of 83 participants. This participant had the serious adverse reaction of kidney injury.

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

What adverse reactions happened during this study?

The most common adverse reaction that happened during this study was skin reaction at the infusion site. The adverse reactions that happened in this study were:

- A skin reaction at the site of the infusion happened in 2.4% of participants who got 1,500 mg of MEDI3902. This was 2 out of 85 participants.
- Increased heart rate happened in 1.2% of participants who got 1,500 mg of MEDI3902. This was 1 out of 85 participants.
- A kidney injury happened in 1.2% of participants who got the placebo. This was 1 out of 83 participants.

How has this study helped patients and researchers?

This study helped researchers learn about using MEDI3902 in people who are on breathing machines and are at risk of developing bacterial pneumonia.

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 MEDI3902 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 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 **"NCT02696902"** into the search box, and click **"Search"**.
- http://www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2015-001706-34"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5470C00004"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 2 Proof-of-concept Study to Evaluate the Efficacy and Safety of MEDI3902 in Mechanically Ventilated Patients for the Prevention of Nosocomial Pneumonia Caused by Pseudomonas aeruginosa

AstraZeneca Protocol Number: D5470C00004

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

CISCRP
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