Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune
Drug Studied: MEDI8897
Study Title: This study was done to learn how MEDI8897 worked and how safe it was in prematurely born infants

Thank you!

Thank you to the caregivers who allowed their infants to take part in the clinical trial for the study drug MEDI8897. You helped researchers learn more about using MEDI8897 to help prevent serious lung infection caused by respiratory syncytial virus in prematurely born infants. Respiratory syncytial virus is also known as RSV.

MedImmune sponsored this study and thinks it is important to share the results of the study with you and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you. We hope it helps you understand and feel proud of your child's important role in medical research.

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

What is happening with the study now?

Each infant was in the study for about 1 year. The entire study lasted for a little more than 2 years. The study started in November 2016 and ended in December 2018.

The study included 1,453 participants in 23 countries: Argentina, Australia, Belgium, Brazil, Bulgaria, Canada, Chile, Czech Republic, Estonia, Finland, France, Hungary, Italy, Latvia, Lithuania, New Zealand, Poland, Spain, South Africa, Sweden, Turkey, the United Kingdom, 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 prevent serious lung infections caused by RSV in infants who are born prematurely. 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.

A virus called respiratory syncytial virus causes respiratory infections in children. In older children and adults, RSV usually causes symptoms similar to the common cold. But in infants and young children, it can cause serious lung infections. These illnesses are called lower respiratory tract infections, also known as LRTIs. Infants born prematurely have a high risk of getting RSV, but all infants can get RSV. The highest risk is during the fall and winter months.

Children at high risk of these lung infections caused by RSV include infants born prematurely, children with chronic lung disease of prematurity, or congenital heart disease. There is a medicine currently used to prevent the lung infections caused by RSV in high risk children. This medicine must be given to infants monthly through the fall and winter months, known as the RSV season. The study drug, MEDI8897, would only need to be given 1 time a year for the entire RSV season. It would also be available for all infants, including those born at full term.

In this study, the researchers wanted to find out how MEDI8897 worked in a large number of prematurely born infants. They also wanted to find out if the infants developed any medical problems during the study.

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

- Did the infants who got MEDI8897 have a lower risk for getting a LRTI caused by RSV?
- What medical problems did the infants have during the study?

To answer the questions in this study, the researchers asked parents and caregivers for the help of healthy infants who were born prematurely. The infants in this study were between a few weeks of age to almost 1 year old and had not been given any other treatment related to RSV.

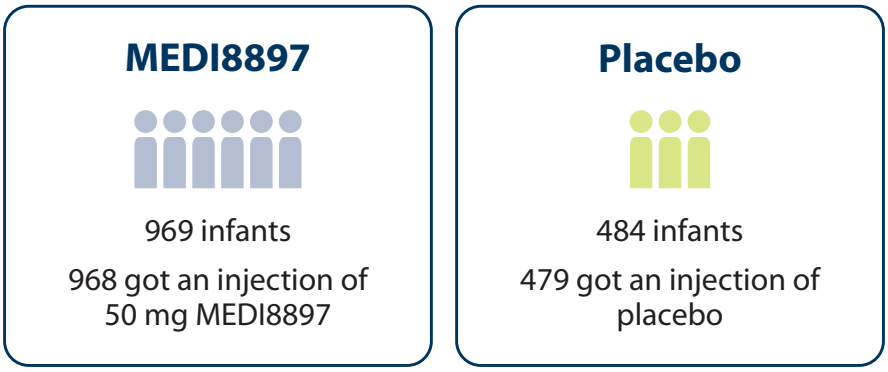
What kind of study was this?

This was a “double-blind” study. This means none of the caregivers, doctors or other study staff knew what study drug each infant received. 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 infants got so they could create a report of the study results.

In this study, the infants got MEDI8897 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 infants who take the drug are actually caused by the drug.

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

In this study, the infants got 1 dose of either MEDI8897 or a placebo as an injection. The dose of MEDI8897 was measured in milligrams, also called mg.



What happened during the study?

Before the infants got any study treatment, the doctors:

- checked the overall health of the infants to make sure that they could join the study
- asked the caregivers about the medical history of the infants and what medications they were getting
- took blood samples from the infants

During the study, the infants visited the study site at least 5 times.

Medical staff at the study site gave the infants the study drug that was randomly chosen for them.

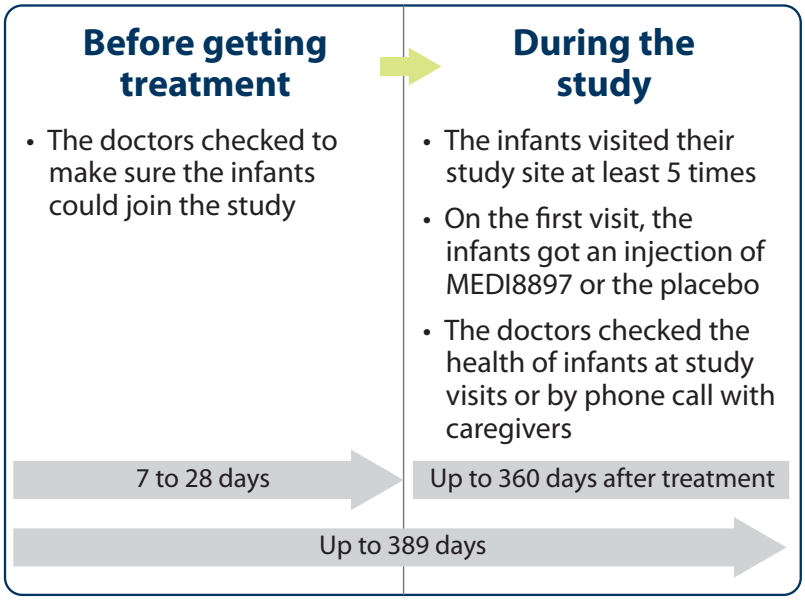
At these visits, the doctors:

- checked the health of the infants
- asked the caregivers about any illnesses, doctor visits, or hospitalizations the infant may have had
- took blood samples from the infants (at 3 of the visits)

The doctors or study staff checked on the health of the infants during the study.

- They called the caregivers every 2 weeks after the day of treatment for the first 150 days after the infants got the treatment.
- Then, they called once a month for the next 210 days.

The chart below shows what happened during the study.



What were the results of the study?

This is a summary of the main results from this study overall. The results each infant had might be different and are not in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. A full report of the study results is also available 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.

Did the infants who got MEDI8897 have a lower risk for getting a serious LRTI?

Yes. The researchers found that fewer infants who got MEDI8897 had LRTIs caused by RSV.

To answer this question, the researchers counted the number of infants who got a LRTI associated with RSV that needed medical attention during the first 150 days after treatment. Any LRTIs associated with RSV that did not need medical attention were not counted in this study.

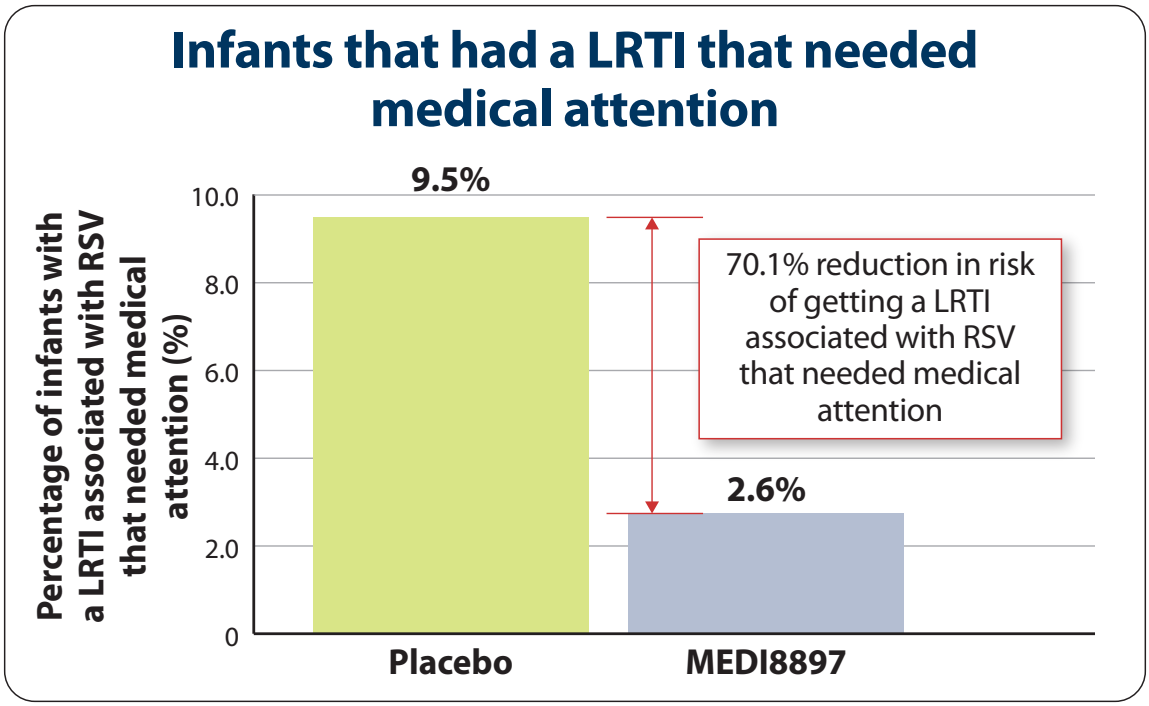
Overall:

- There were 2.6% of infants in the MEDI8897 group who had a LRTI associated with RSV. This was 25 out of 969 participants.
- There were 9.5% of participants in the placebo group who had a LRTI associated with RSV. This was 46 out of 484 participants.

Researchers calculated the risk of the participants needing medical attention for a LRTI. They compared this risk between those that got MEDI8897 or got the placebo.

There was a 70.1% reduction in the risk of having a LRTI associated with RSV that needed medical attention for participants who got MEDI8897 compared with participants who got the placebo.

The graph below shows these results.



What medical problems did infants have during the study?

This section is a summary of the medical problems the infants had during the study that the study doctors thought might be related to the 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.

1,453 participants enrolled in the study but 6 of them left the study before receiving any study drug or placebo. Only the remaining 1,447 participants were included in the safety assessment.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

- Overall, 2.2% of participants had adverse reactions during the study. This was 32 out of 1,447 participants.
- 2.3% of the participants who got MEDI8897 had adverse reactions during the study. This was 22 out of 968 participants.
- 2.1% of the participants who got the placebo had adverse reactions during the study. This was 10 out of 479 participants.

Only a single injection of the study drug was given. So, no participants stopped taking the study treatment because of adverse reactions they had during the study.

What adverse reactions did the participants have?

The most common adverse reactions were general rash and a strong desire for sleep.

The table on the next page shows the most common adverse reactions that happened during the study.

Most common adverse reactions during the study		
	MEDI8897 (out of 968 participants)	**Placebo (out of 479 participants)**
General rash	0.4% (4)	0.4% (2)
Very strong desire for sleep	0.4% (4)	0.0% (0)
Irritability	0.2% (2)	0.2% (1)
Vomiting	0.0% (0)	0.4% (2)
Fever	0.1% (1)	0.2% (1)
Sore throat	0.1% (1)	0.2% (1)
Decreased appetite	0.1% (1)	0.2% (1)
Iron deficiency	0.0% (0)	0.2% (1)
Red skin	0.0% (0)	0.2% (1)
Rash – small, flat red spots under the skin (also known as petechiae)	0.0% (0)	0.2% (1)
General sleepiness	0.0% (0)	0.2% (1)
Decreased activity	0.1% (1)	0.0% (0)
A lump on the skin at the injection site	0.1% (1)	0.0% (0)
Injection site swelling	0.1% (1)	0.0% (0)
Injection site pain	0.1% (1)	0.0% (0)
Injection site reaction	0.1% (1)	0.0% (0)
Tiny, round, flat spots on the skin	0.1% (1)	0.0% (0)
Rash – with small, flat, red areas of discoloration (also known as macular rash)	0.1% (1)	0.0% (0)
Rash – red area of discoloration covered with small bumps (also known as a maculo-papular rash)	0.1% (1)	0.0% (0)
Eczema	0.1% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about using MEDI8897 to prevent serious LRTIs caused by RSV in prematurely born infants.

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 MEDI8897 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 **"NCT02878330"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home and Search"**, then type **"2016-001677-33"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5290C00003"** into the search box, and click **"Find a Study"**.

Full study title: A Phase 2b Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Preterm Infants

National Clinical Trials number: NCT02878330

AstraZeneca Protocol Number: D5290C00003

MedImmune, a subsidiary of AstraZeneca, sponsored this study and has its headquarters in Gaithersburg, United States.

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
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