Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research sponsor: MedImmune, LLC

Drug studied: MEDI3250 vaccine

Study title: A study to learn more about the safety of the MEDI3250 flu vaccine

Thank you!

Thank you to the participants in the clinical study for the vaccine MEDI3250. All of the participants helped researchers learn more about using the MEDI3250 vaccine to prevent influenza, also known as the flu.

MedImmune, LLC 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 has finished. The participants were in the study for about 6.5 months and the entire study took 7 months to finish.

The study started in May 2017 and ended in December 2017. The study included 300 participants in 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?

The flu is an infection that can cause medical problems, including fever and muscle aches. There are several different types of flu, and each type is known as a “strain”.

The study vaccine, MEDI3250, was created to defend the body against 1 strain of the flu. The MEDI3250 vaccine is a medicine that has a weakened version of a virus in it. Doctors give patients vaccines so that their bodies can fight the virus and help prevent disease in the future.

Every year, researchers make a new vaccine against the flu. Before the MEDI3250 vaccine can be approved for patients to take, researchers do a clinical study to find out how safe it is.

Researchers already did studies that showed how the MEDI3250 vaccine helped prevent the flu. In this study, the researchers wanted to find out more about the safety of the MEDI3250 vaccine.

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

- Did the participants who took the MEDI3250 vaccine have more or fewer symptoms compared to the participants who took the placebo?
- What medical problems did participants have during the study?

To answer the questions in this study, researchers asked for the help of healthy men and women. The participants in this study were 18 to 49 years old.

What kind of study was this?

This was a “double-blind” study. This means that none of the participants, doctors, or other study staff knew which group each participant was in. Some studies are done this way because knowing what group the participants are in can affect the results of the study. When the study ended, the research sponsor found out which group each participant was in so they could create a report of the study results.

The participants in this study were either in the vaccine group and took the MEDI3250 vaccine, or in the placebo group and took a placebo. A placebo looks like a vaccine 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 vaccine are actually caused by the vaccine.

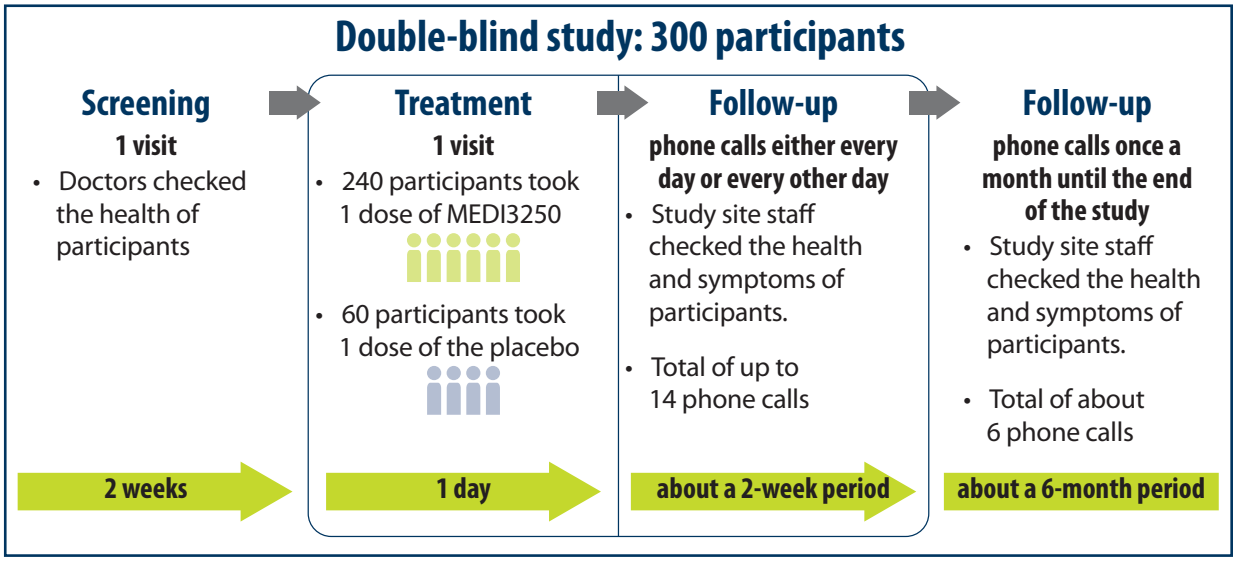
A computer program was used to randomly choose the group each participant was in. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each group is as accurate as possible.

What happened during the study?

Before the study started, the doctors gave the participants a physical exam, including checking their temperature. The doctors also asked the participants about their medical history, how they were feeling, and what medicines they were taking. The doctors made sure the participants did not have the flu before they were given the MEDI3250 vaccine or placebo.

During the study, the participants visited their study site once. They took 1 dose of either the MEDI3250 vaccine or the placebo as a nasal spray. For the first 2 weeks after this visit, the study site staff called the participants either every day or every other day to ask them about their health and symptoms. After that, the study site staff called the participants once a month until the end of the study to ask them about their health and symptoms. Participants got a total of up to 20 phone calls during the study.

The figure below shows how the study was done.



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. 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 change.

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

Did the participants who took the MEDI3250 vaccine have more or fewer symptoms compared to the participants who took the placebo?

In general, the participants who took the MEDI3250 vaccine had slightly more symptoms compared to the participants who took the placebo.

To answer this question, the researchers studied:

- the number of participants who developed a fever of 101°F or higher within 1 week of taking the MEDI3250 vaccine or placebo
- the number of participants who developed symptoms within 1 week of taking the MEDI3250 vaccine or placebo
- the number of participants who developed symptoms within 2 weeks of taking the MEDI3250 vaccine or placebo

Within 1 week of taking the MEDI3250 vaccine or placebo, the researchers found that:

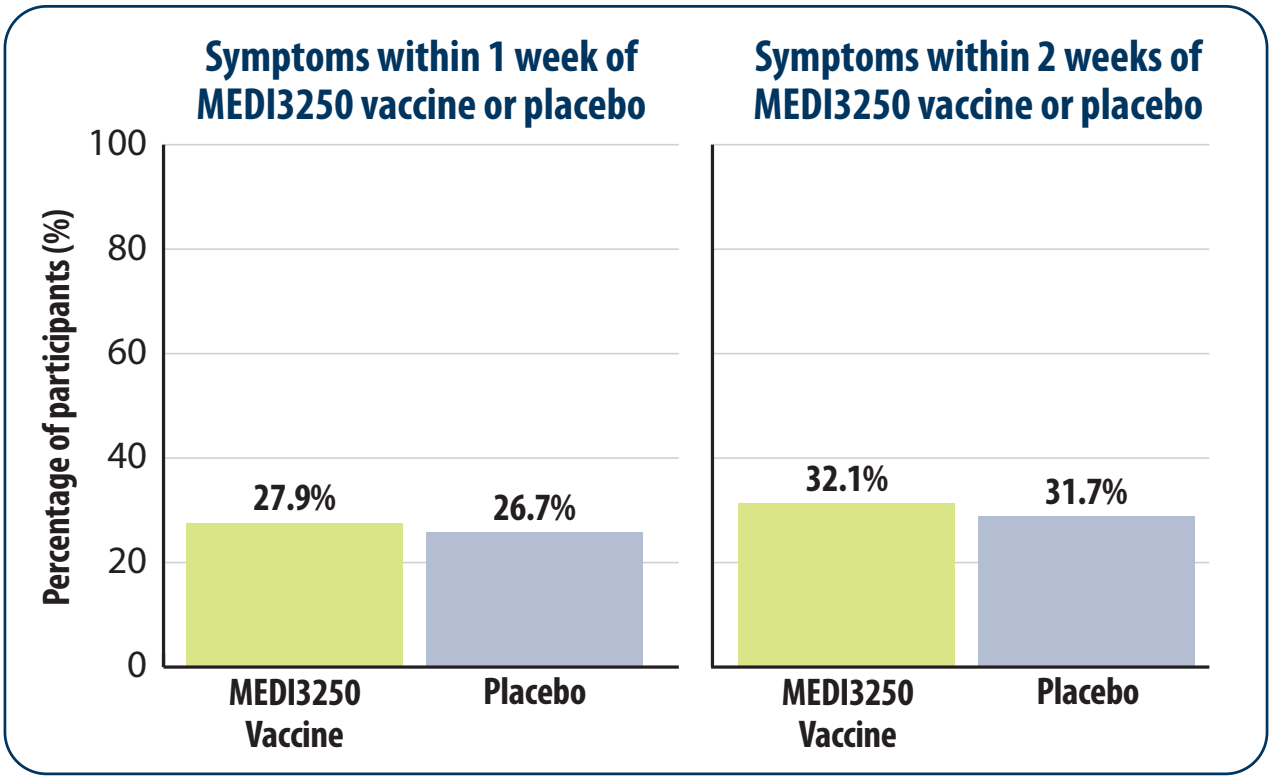
- None of the participants in either group developed a fever of 101°F or higher.
- 27.9% of participants who took the MEDI3250 vaccine developed symptoms. This was 67 out of 240 participants.
- 26.7% of participants who took the placebo developed symptoms. This was 16 out of 60 participants.

Within 2 weeks of taking the MEDI3250 vaccine or placebo, the researchers found that:

- 32.1% of participants who took the MEDI3250 vaccine developed symptoms. This was 77 out of 240 participants.
- 31.7% of participants who took the placebo developed symptoms. This was 19 out of 60 participants.

The symptoms that the participants had were headache, runny nose, sore throat, tiredness, cough, muscle aches, chills, vomiting, and fever.

The figure below shows these results.



What medical problems did participants have during the 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 MEDI3250 vaccine. 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 vaccine. A lot of research is needed to know whether a vaccine causes an adverse reaction. The websites listed at the end of this summary may have more information about the adverse reactions or other medical problems that happened during the study.

How many participants had serious adverse reactions?

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

None of the participants died during the study.

How many participants had adverse reactions?

There were 2.7% of participants who had adverse reactions during the study. This was 8 out of 300 participants.

There were 3.3% of participants who took the MEDI3250 vaccine who had adverse reactions during the study. This was 8 out of 240 participants.

None of the participants who took the placebo had adverse reactions during the study.

None of the participants stopped treatment because of adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction was nasal congestion.

The table below shows the adverse reactions that happened during the study.

Adverse reactions		
	MEDI3250 vaccine (Out of 240 participants)	**Placebo (Out of 60 participants)**
Nasal congestion	0.8% (2)	0.0% (0)
Bloody nose	0.4% (1)	0.0% (0)
Ear congestion	0.4% (1)	0.0% (0)
Producing extra phlegm	0.4% (1)	0.0% (0)
Rash on arms and hands	0.4% (1)	0.0% (0)
Sneezing	0.4% (1)	0.0% (0)
Stiffness in neck	0.4% (1)	0.0% (0)
Swelling in the throat	0.4% (1)	0.0% (0)

How has this study helped patients and researchers?

These results helped researchers learn more about the MEDI3250 vaccine and if it is safe for people to take to prevent them from getting the flu.

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 the MEDI3250 vaccine like this one are planned and will be carried out every year.

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 **"NCT03158038"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D2560C00014"** into the search box, and click **"Find a Study"**.

The full title of your study is: A Phase 4, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety of 1 New 6:2 Influenza Virus Reassortant in Adults

MedImmune Protocol number: D2560C00014

MedImmune, LLC, a member of the AstraZeneca Group, sponsored this study and has its headquarters at One MedImmune Way, Gaithersburg, MD 20878 USA.

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 participants.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

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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