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 study 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 months and the entire study took up to 7 months to finish.

The study started in June 2018 and ended in December 2018. 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 2 strains of the flu. The study vaccine has weakened versions of these viruses in it. Doctors give patients vaccines so that their bodies can fight viruses 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 in other healthy participants that showed how the study vaccine helped prevent them from getting the flu. In this study, the researchers wanted to find out more about the safety of this vaccine.

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

- How many participants had a fever or other symptoms after getting study treatment?
- What medical problems did participants have during the study?

To answer the questions in this study, the 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 none of the participants, doctors, or other study staff knew what treatment each participant 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 the participants got so they could create a report of the study results.

The participants in this study were given either the study vaccine or a placebo. The placebo looked like a vaccine but did not have any medicine in it. The researchers used a placebo to help make sure any of the effects they saw in the participants who got the vaccine were actually caused by the vaccine.

A computer program was used to randomly choose whether each participant was in the MEDI3250 treatment group or the placebo treatment group. 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?

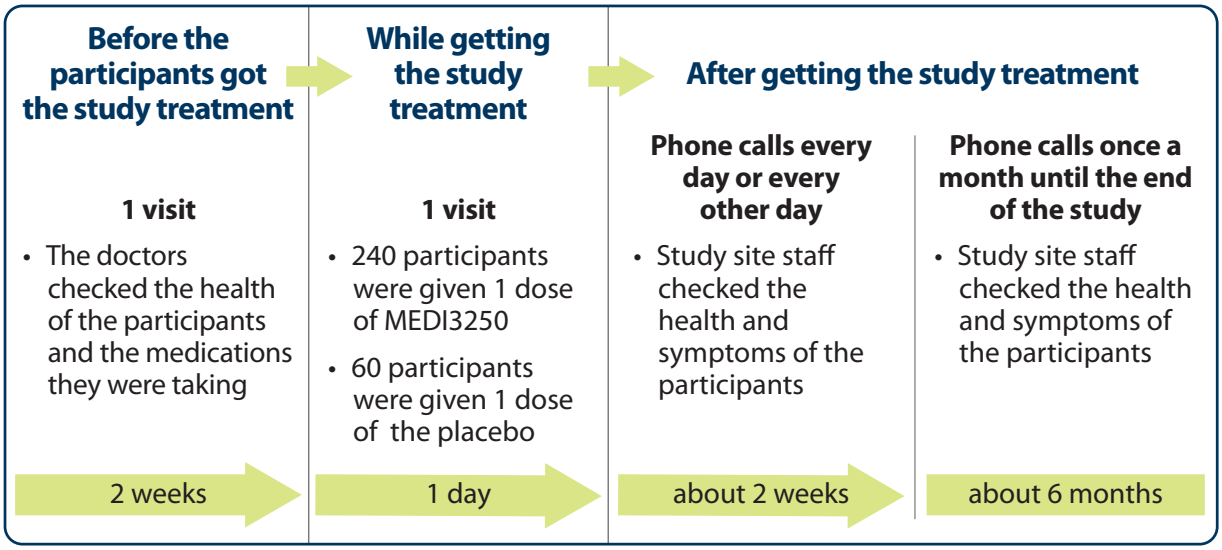
Before the participants took the study treatment, the doctors gave the participants a physical exam and checked their temperature. The doctors also asked the participants about their medical history, how they were feeling, and what medicines they were taking.

The doctors made sure the participants did not have the flu before they were given the study vaccine or the placebo.

While getting study treatment, the participants visited their study site once. They were given 1 dose of either the study vaccine or the placebo as a nasal spray.

- For the first 2 weeks after this visit, the study site staff called the participants every day or every other day to ask them about their health and symptoms and the medications they were taking.
- 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.

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.

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

How many participants had fever or symptoms after getting study treatment?

Overall, the number of participants with symptoms was slightly higher in the group who were given the study vaccine compared to the group who were given the placebo.

The researchers studied:

- the number of participants in each group who developed a fever of 101 degrees or higher within 1 week of getting the study treatment
- the number of participants in each group who developed symptoms within 1 week of getting the study treatment
- the number of participants in each group who developed symptoms within 2 weeks of getting the study treatment

A “symptom” could be any of these:

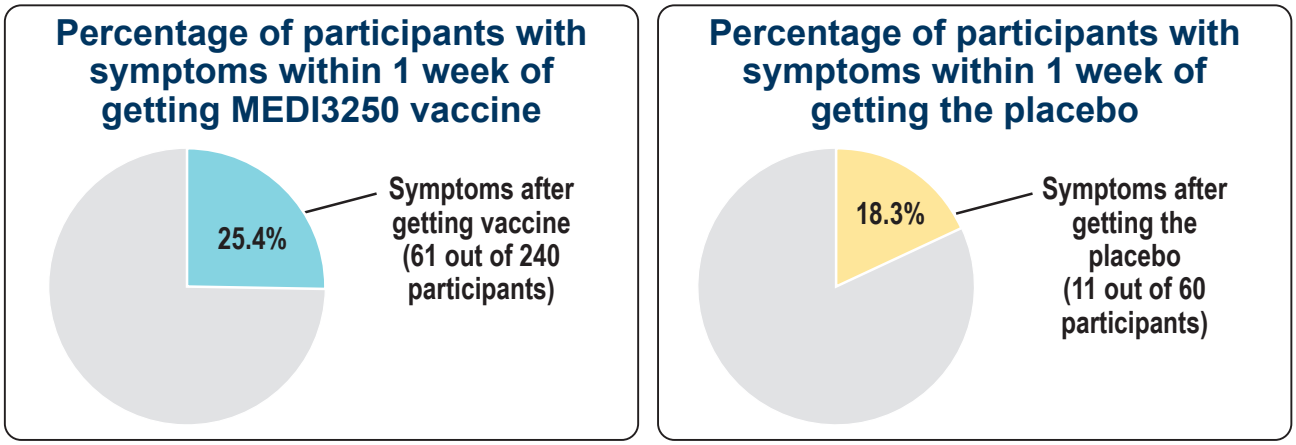
- headache
- runny nose
- sore throat
- tiredness
- cough
- muscle aches
- chills
- vomiting
- fever of 100 degrees or higher

Within 1 week

The researchers found that within 1 week of getting the study vaccine or the placebo:

- None of the participants in either group developed a fever of 101 degrees or higher.
- 25.4% of participants who got the study vaccine developed symptoms. This was 61 out of 240 participants.
- 18.3% of participants who got the placebo developed symptoms. This was 11 out of 60 participants.

The figure below shows these results.

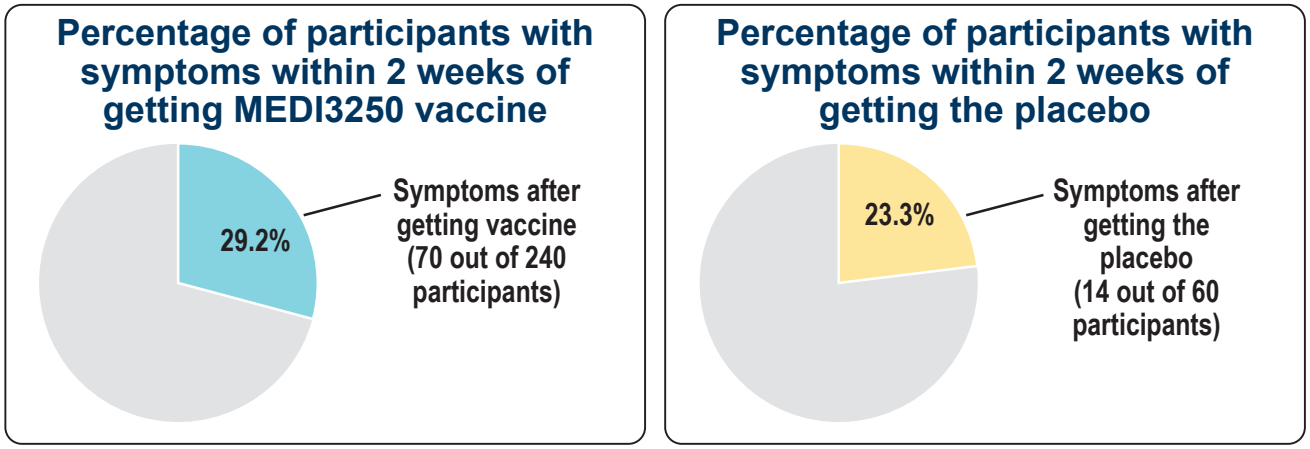


Within 2 weeks

The researchers found that within 2 weeks of getting the study vaccine or the placebo:

- 29.2% of participants who got the study vaccine developed symptoms. This was 70 out of 240 participants.
- 23.3% of participants who got the placebo developed symptoms. This was 14 out of 60 participants.

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 study 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 due to serious adverse reactions during the study.

How many participants had adverse reactions?

There were 0.6% of participants who had adverse reactions during the study. This was 2 out of 300 participants.

- 0.4% of participants who got the study vaccine had adverse reactions during the study. This was 1 out of 240 participants. This participant had throat irritation.
- 1.7% of participants who got the placebo had adverse reactions during the study. This was 1 out of 60 participants. This participant had nasal itchiness.

Only a single dose of the study vaccine was given. So, no participants stopped getting the study vaccine because of adverse reactions they had during the study.

How has this study helped patients and researchers?

These results helped researchers learn more about the safety of MEDI3250 vaccine in healthy 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 the MEDI3250 vaccine 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 **"NCT03564444"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D2560C00015"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase 4, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety of 2 New 6:2 Influenza Virus Reassortants in Adults

National Clinical Trials number: NCT03564444

MedImmune Protocol Number: D2560C00015

MedImmune, LLC, a member of the AstraZeneca Group, sponsored this study and has its headquarters at One MedImmune Way, Gaithersburg, MD 20837 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 (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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