Clinical Study Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, LLC

Drug Studied: MEDI3250

Study Title: A study to learn more about how different types of MEDI3250 flu vaccine act in healthy young children

Thank you!

Thank you to the participants who took part in the clinical study for MEDI3250, and to their parents or caregivers. All of the participants helped researchers learn more about using MEDI3250 to prevent influenza, also called 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. We hope it helps the participants' parents or caregivers understand and feel proud of their 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 child's study site.

What is happening with the study now?

The participants were in the study for up to 3 to 4 months and the entire study took 5 months to finish. The study started in May 2017 and ended in September 2017. The study included 200 children 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 a virus that can cause a lot of medical problems, including fever and muscle aches. There are many different types of flu viruses, but this study focused on 2 types. Each type of virus has 2 different groups of strains.

- Type A virus: A/H1N1 and A/H3N2 strains
- Type B virus: B/Yamagata and B/Victoria strains

The vaccine in this study, called MEDI3250, was made to defend the body against different strains of the flu virus. The MEDI3250 vaccine has weak versions of certain strains of the flu virus in it. Vaccines cause the body to make antibodies. Antibodies are proteins in the body that fight infection and help prevent disease in the future.

Researchers already did studies that showed how the MEDI3250 vaccine worked. In this study, the researchers wanted to find out more about how MEDI3250 acted in children who got 1 of 3 different types of the MEDI3250 vaccine.

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

- Which vaccine increased antibodies to each flu strain the most?
- What medical problems did the participants have during the study?

To answer the questions in this study, researchers asked for the help of 200 healthy young male and female children. The children in this study were between 23 and 48 months 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 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 vaccine each participant got so they could create a report of the study results.

The participants in this study got 1 of 3 different types of MEDI3250 vaccine. Each type of the MEDI3250 vaccine had different strains of the flu virus in it.

Vaccine A MEDI3250 with 3 strains	Vaccine B MEDI3250 with 4 strains	Vaccine C MEDI3250 with 4 strains
 67 participants 	 66 participants 	 67 participants 
• Older A/H1N1 strain • Older A/H3N2 strain • B/Yamagata strain	• Older A/H1N1 strain • Older A/H3N2 strain • B/Yamagata strain • B/Victoria strain	• Newer A/H1N1 strain • Newer A/H3N2 strain • B/Yamagata strain • B/Victoria strain

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

What happened during the study?

Before the study started, the doctors did exams to make sure the participants could join the study. The doctors also made sure the participants did not have the flu.

During the study, the participants visited their study site 11 times. They got 2 doses of the MEDI3250 vaccine as a nasal spray. The first dose was given on their first visit, and the second dose was given 28 days later. Each dose was given as 2 sprays. 1 spray was given into each nostril.

The doctors:

- did exams to check the participants' health
- collected nasal samples using a swab at all study visits
- took blood samples before each dose and 56 days after the first dose of the vaccine

At each visit and during telephone contacts, the doctors or study site staff asked the participants' parents or caregivers about:

- the participants' health and medical history
- how the participants were feeling
- what medicines the participants were getting

The figure below shows how the study was done.

Double-blind study: 200 participants

Before the study	During the study
• The participants visited the study site 1 time. • The doctors checked the participants' health.	• The participants visited the study site 11 times. • The participants got a dose of MEDI3250 on their first visit and another dose 28 days later. • The doctors checked the participants' health, collected nasal samples using a swab, and took blood samples.

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.

Which vaccine increased antibodies to each flu strain the most?

The researchers wanted to know which vaccine increased antibodies to each flu strain the most. They did this by taking blood samples from each participant before they got MEDI3250, 28 days after they got MEDI3250, and 56 days after they got MEDI3250.

In this study, participants' antibodies were considered to be increased if there were at least 4 times more antibodies in their blood after getting MEDI3250.

A/H1N1 strain

The main purpose of the study was to look at antibody responses to the A/H1N1 strain. More participants who got Vaccine C had increased antibodies to the A/H1N1 strain compared with participants who got Vaccine A or Vaccine B.

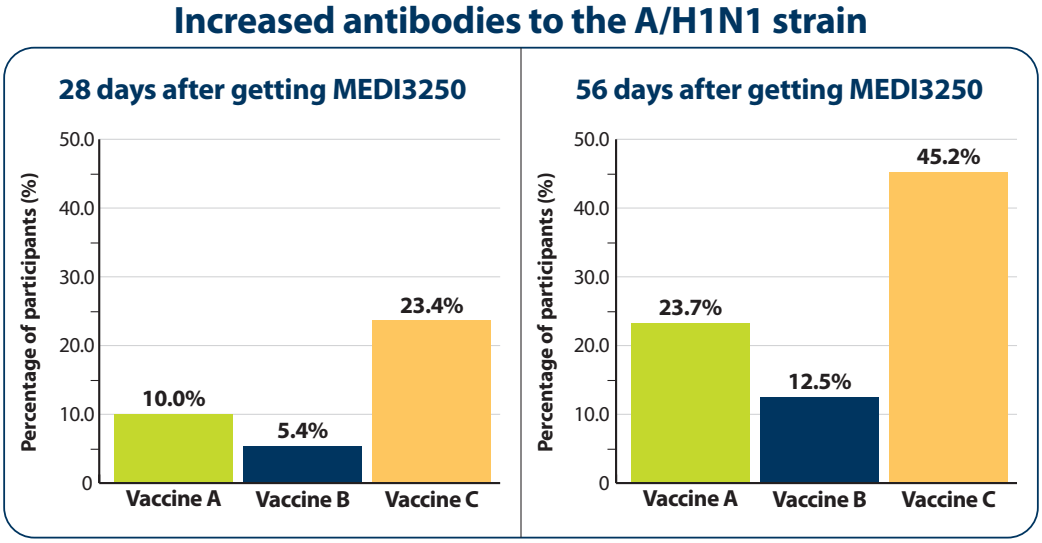
At 28 days after getting MEDI3250:

- 10.0% of participants who got Vaccine A had increased antibodies
- 5.4% of participants who got Vaccine B had increased antibodies
- 23.4% of participants who got Vaccine C had increased antibodies

At 56 days after getting MEDI3250:

- 23.7% of participants who got Vaccine A had increased antibodies
- 12.5% of participants who got Vaccine B had increased antibodies
- 45.2% of participants who got Vaccine C had increased antibodies

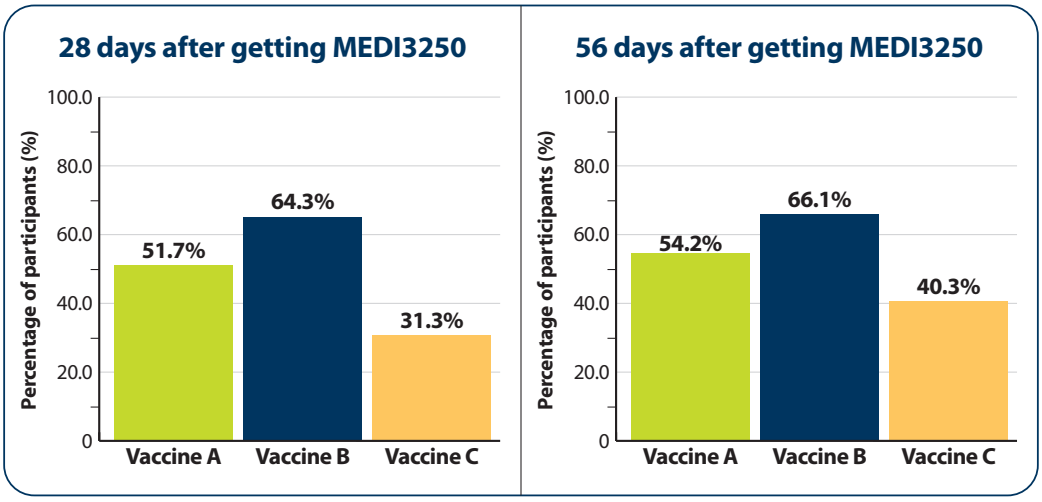
The figure below shows these results.



A/H3N2 strain

More participants who got Vaccine A and Vaccine B had increased antibodies to the A/H3N2 strain compared with participants who got Vaccine C.

The figure below shows these results.

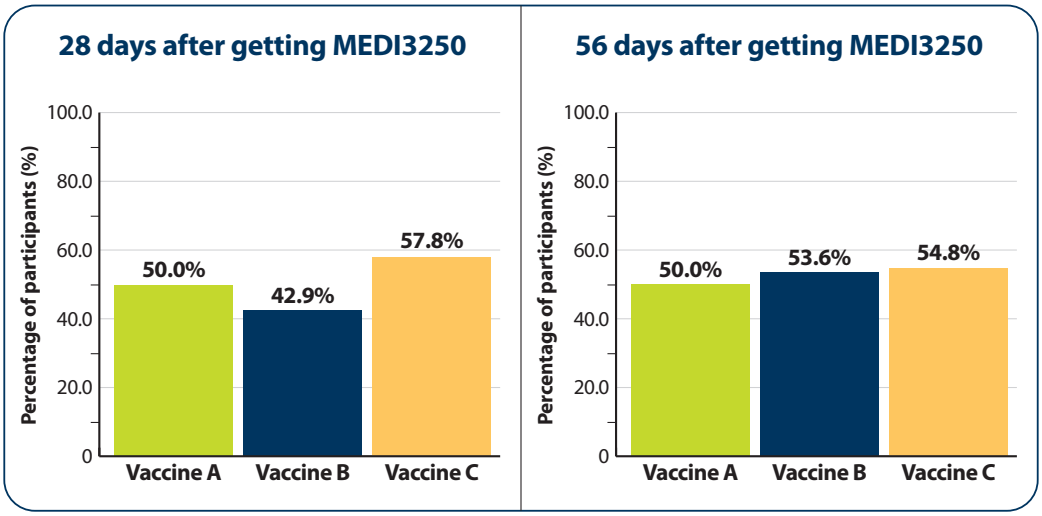


B/Yamagata strain

A similar number of participants who got Vaccine A, Vaccine B, and Vaccine C had increased antibodies to the B/Yamagata strain.

The figure below shows these results.

Increased antibodies to the B/Yamagata strain

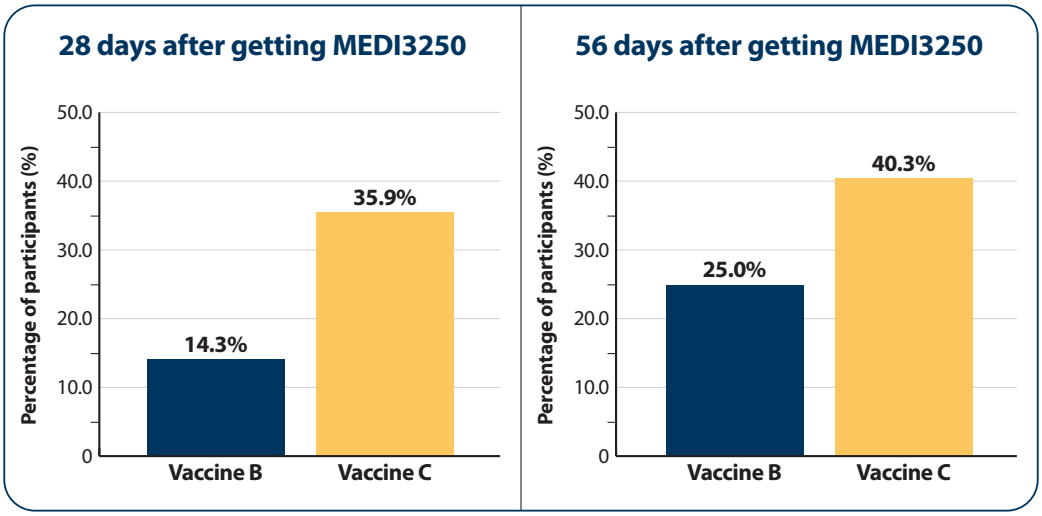


B/Victoria strain

More participants who got Vaccine C had increased antibodies to the B/Victoria strain compared with participants who got Vaccine B. The B/Victoria strain was not included in Vaccine A so there was no antibody responses to look at.

The figure below shows these results.

Increased antibodies to the B/Victoria strain



What medical problems did the participants have during the study?

This section is a summary of the medical problems the participants had during the study that the doctors thought might be related to MEDI3250. 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, and none of the participants died.

How many participants had adverse reactions?

There were 5.0% of participants who had adverse reactions during the study that were thought to be possibly related with getting MEDI3250. This was 10 out of 200 participants. About the same number of participants in each vaccine group had adverse reactions after getting MEDI3250.

The table below shows the number of participants with adverse reactions during the study.

	Vaccine A (Out of 67 participants)	Vaccine B (Out of 66 participants)	Vaccine C (Out of 67 participants)
How many participants had adverse reactions during the study?	7.5% (5)	3.0% (2)	4.5% (3)

None of the participants stopped getting MEDI3250 because of adverse reactions.

What adverse reactions did the participants have?

The most common adverse reaction that was thought to be possibly related to getting MEDI3250 was ear infection. This happened in 3.0% of the participants who got Vaccine C. This was 2 out of 67 participants.

There were other adverse reactions, but these happened only in 1 participant in any of the vaccine groups.

How has this study helped participants and researchers?

These results helped researchers learn more about how different types of the MEDI3250 vaccine act and how they affect antibodies in healthy young children.

Researchers look at the results of many studies to decide which vaccines 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 this form of the MEDI3250 vaccine 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 **"NCT03143101"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D2560C00013"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase 4 Double-blind Study to Evaluate the Shedding and Immunogenicity of Trivalent and Quadrivalent Formulations of FluMist in Children 24 to < 48 Months of Age

MedImmune Protocol Number: D2560C00013

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.

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