Clinical Trial RESULTS

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, LLC
Drugs Studied: MEDI3250 (FluMist® Quadrivalent)
National Clinical Trial #: NCT02473510
Protocol #: D2560C00009
Study Date: June 2015 to January 2016
Short Study Title: A study to determine the safety of a new investigational form of FluMist® in healthy adults

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for a new form of FluMist®. This vaccine is being developed to prevent influenza, or the flu. You and all of the participants helped researchers learn about the safety of this form of FluMist®.

MedImmune, LLC, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

What has happened since my study ended?

Your study started in June 2015 and ended in January 2016. It included 300 participants at 3 study sites in the United States. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Before a new drug can be approved, research must be done to show that it is safe and effective. The FluMist® Quadrivalent nasal spray vaccine is approved by the Food and Drug Administration, known as the FDA, for the prevention of influenza, which is commonly referred to as the flu. The flu is caused by a virus that infects your nose, throat, and lungs. The main symptoms of the flu are fever, chills, muscle aches, cough, sore throat, stuffy nose, and tiredness. Each year different strains of flu can cause illness so all influenza vaccines have to be adjusted to protect people against these new strains. FluMist® Quadrivalent contains 4 vaccine strains but each year all new strains have to be tested in healthy people for safety before the vaccine can be used.

In this study, researchers tested 3 vaccine strains. Two strains were new. The third was a newer version of a strain used in the 2015 flu season vaccine. Researchers compared these 3 vaccine strains with a placebo. The placebo looked like the flu vaccine but contained no real medicine. Researchers use placebos in studies to compare the results for participants who take study drugs with the results for participants who take no medicine at all.

Researchers wanted to know:

- Were the fever rates comparable between the participants who got the 3 strain vaccine and those who got the placebo?
- Did more participants have vaccine side effects within 7 days of getting the 3 strain vaccine, compared to the placebo?
- What medical problems did participants have after getting the 3 strain vaccine?

Your study included healthy men and women who were 18 to 49 years old.

What kind of study was this?

Your study was a "double-blind" study. This means that none of the participants, study doctors, or staff knew what treatment each participant received. Some studies are done this way because knowing what treatment each participant is getting can affect the results of the study. This way, the results are looked at fairly.

Participants got either the 3 strain vaccine or the placebo in a single-dose treatment. The separating of participants into different groups was done by chance, like rolling dice.

What happened during the study?

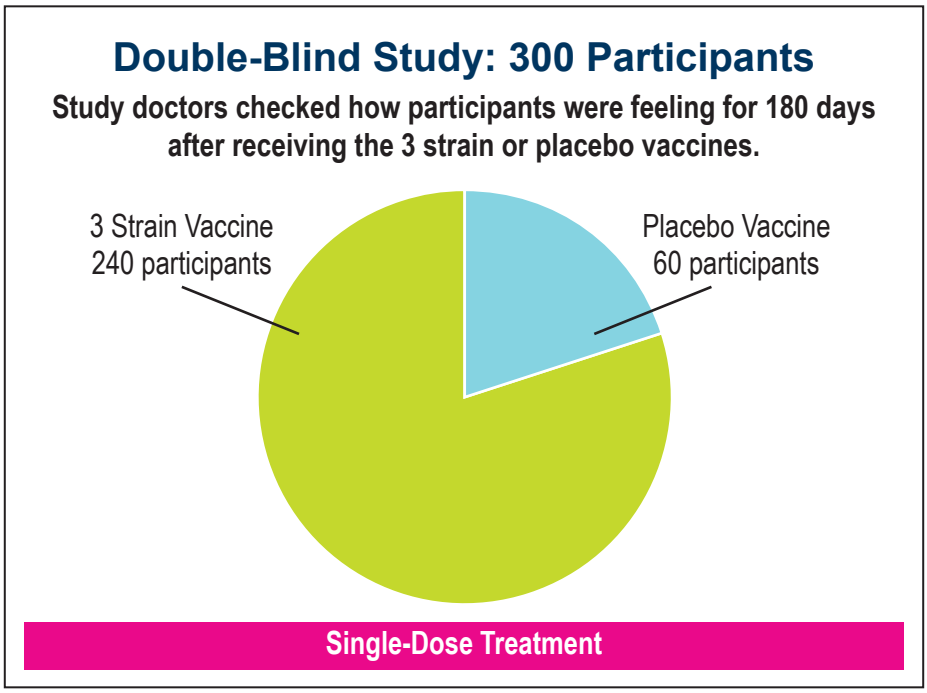
You and other participants were in the study for up to 7 months.

First, to see if you could join the study, researchers did a physical exam, including checking your height, weight, and temperature. They asked about your medical history, how you were feeling, and what medicines you were taking. If you are female, you had a blood or urine test to make sure you were not pregnant.

Once you joined the study, you were randomly assigned to get either the 3 strain vaccine or placebo. The vaccine or placebo was sprayed into your nose. For every 5 participants, 4 received the 3 strain vaccine and 1 received the placebo. Out of 300 participants, 240 got the 3 strain vaccine and 60 got the placebo.

Study doctors checked how you were feeling for 180 days, or 6 months, after getting the vaccine or placebo. They called you to learn what other medicines you were taking and if you had any new medical problems.

The figure below shows how the study was done.



What were the study results?

Below is a summary of the results of some of the questions the researchers asked during this study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with the 3 strain vaccine are planned in 2017.

Were the fever rates comparable between the participants who got the 3 strain vaccine and those who got the placebo?

Yes. Rates of fever were comparable between the 3 strain vaccine group and the placebo group. One out of 240 participants (0.4%) who got the 3 strain vaccine reported a fever. No participants who got placebo reported a fever.

Overall, because the rates of fever were so low, the researchers concluded the 3 strain vaccine was unlikely to be an important cause of fever.

Did more participants have other vaccine side effects within 7 days of getting the 3 strain vaccine, compared to the placebo?

Yes. Overall, more participants who got the 3 strain vaccine reported tiredness, runny nose, muscle aches, sore throat, and headache, compared to those who got the placebo. The frequency of these side effects is comparable with those seen in previous experiments and is thought to be a sign of the body making a protective response. The body protects itself by creating antibodies, which are formed to fight these types of side effects.

The table below shows how many participants had at least 1 flu symptom.

Symptom	Vaccine (Out of 240 participants)	Placebo (Out of 60 participants)
Headache	38 (15.8%)	8 (13.3%)
Runny nose	37 (15.4%)	7 (11.7%)
Sore throat	22 (9.2%)	4 (6.7%)
Tiredness	16 (6.7%)	1 (1.7%)
Muscle aches	11 (4.6%)	1 (1.7%)
Cough	8 (3.3%)	2 (3.3%)
Chills	5 (2.1%)	2 (3.3%)
Vomiting	1 (0.4%)	0 (0.0%)

Participants reported similar symptoms within 14 days of getting the vaccine or placebo.

What medical problems did participants have?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, researchers keep track of all medical problems that participants have during the study. These medical problems are called "adverse events". They may or may not be caused by the study drug.

How many participants had medical problems in the study?

Overall, 16 participants (5.3%) had at least 1 medical problem. Thirteen out of the 240 participants (5.4%) who took the vaccine had at least 1 medical problem, and 3 out of 60 participants (5.0%) who took placebo had at least 1 medical problem.

The table below shows how many participants had medical problems during the study by treatment group.

	Vaccine (Out of 240 participants)	Placebo (Out of 60 participants)
How many participants had medical problems?	13 (5.4%)	3 (5.0%)
How many participants had serious medical problems?	1 (0.4%)	0 (0.0%)

How many participants had serious medical problems?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospital care.

One participant (0.4%) had a serious medical problem, a blood clot in the lungs, 88 days after getting the vaccine. This participant was taking another medication which can cause blood clots and the study doctors do not think this problem was related to the vaccine.

No participants died during this study, and no participants stopped taking the study drug because of medical problems.

What were the most common medical problems in the study?

The table below shows the most common medical problems that happened within 7 days of getting the vaccine or placebo. In both the 3 strain vaccine group and the placebo group in this study, nasal congestion was the most common medical problem.

Common Medical Problems	Vaccine (Out of 240 participants)	Placebo (Out of 60 participants)
Nasal congestion	5 (2.1%)	2 (3.3%)
Sneezing	2 (0.8%)	0 (0.0%)
Rash	1 (0.4%)	1 (1.7%)
Increased flow of tears	1 (0.4%)	0 (0.0%)
Diarrhea	1 (0.4%)	0 (0.0%)
Nausea	1 (0.4%)	0 (0.0%)
Strep throat	1 (0.4%)	0 (0.0%)
Sunburn	1 (0.4%)	0 (0.0%)
Pain in jaw	1 (0.4%)	0 (0.0%)
Productive cough	1 (0.4%)	0 (0.0%)

Participants reported similar medical problems within 14 days of getting the vaccine or placebo.

Where can I learn more about this clinical study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02473510.

Official study title: A Phase 4, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety of 3 New 6:2 Influenza Virus Reassortants in Adults

MedImmune, LLC, the sponsor of this study, is a member of the AstraZeneca Group of companies and has its headquarters at 1800 Concord Pike, Wilmington, DE 19850. The phone number for the AstraZeneca Information Center is 1-877-240-9479.

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.

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 participants for clinical trials, nor is it involved in conducting clinical trials.

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