Clinical Trial Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, LLC
Vaccine Studied: FluMist® Quadrivalent
National Clinical Trial #: NCT02743117
Protocol #: D2560C00012
Study Date: May 2016 to November 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 other participants helped researchers learn if this form of FluMist is safe to take.

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 May 2016 and ended in November 2016. The study 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 vaccine can be approved, research must be done to show that it is safe and effective. FluMist is a nasal spray vaccine that was developed to treat influenza, which is commonly called the flu. The flu is caused by a virus that infects your nose, throat, and lungs. Some symptoms of the flu are fever, chills, muscle aches, cough, sore throat, stuffy nose, and tiredness.

Each year, different or new strains of flu can cause illness. So, all flu vaccines have to be adjusted to protect people against these different or new strains. In this study, researchers tested 1 strain of the FluMist vaccine.

If the results of this study showed that this 1-strain vaccine is safe, then this 1-strain vaccine might be able to be combined with other flu strains to make a new FluMist nasal spray.

In this study, researchers compared the 1-strain vaccine to a placebo. The placebo looked like the flu vaccine but contained no real medicine. Researchers use a placebo so that they can compare the results of participants who get study drugs with the results of participants who get study drugs.

In your study, researchers wanted to know:

- Did more participants who got the 1-strain vaccine have a fever in the first 7 days after getting the vaccine compared to participants who got the placebo?
- Did more participants who got the 1-strain vaccine have certain symptoms in the first 7 and the first 14 days compared to participants who got the placebo?
- What medical problems, if any, did participants have after getting the 1-strain vaccine or the placebo?

What kind of study was this?

Your study was a "double-blind" study. This means that none of the participants, researchers, or staff knew what treatment each participant got. Some studies are done this way because knowing what treatment each participant is getting might affect the results of the study. This way, the results are looked at fairly. You and the other participants got either the 1-strain vaccine or the placebo. Which treatment participants got was decided by chance, like rolling dice. For every 4 participants that got the 1-strain vaccine, 1 participant got a placebo.

Your study included 300 healthy men and women who were 18 to 49 years old.

What happened during the study?

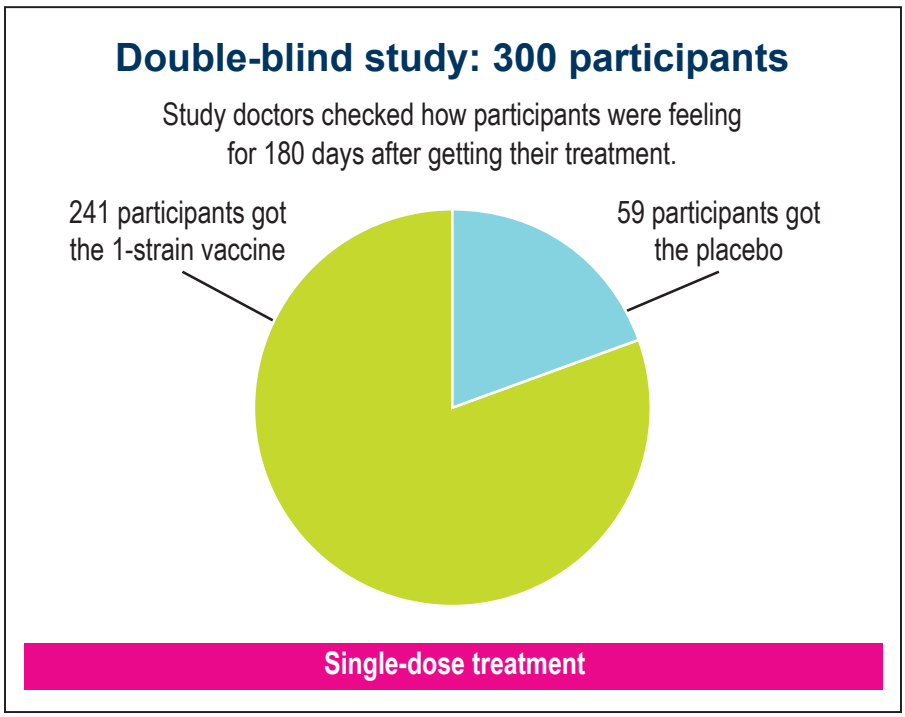
You and the other participants were in the study for up to 7 months.

Before the study started, study doctors did a physical examination, which included checking your height, weight, and body temperature. Study doctors also asked about your medical history, how you were feeling, and what medicines you were taking. If you are female, study doctors checked to see if you were pregnant.

After the study period was over, participants got either 1 dose of the 1-strain vaccine or the placebo. Right before you got the 1-strain vaccine or a placebo, study doctors did another physical examination. Study doctors also asked how you were feeling, if you took any new medicines, and if you developed any new diseases. If you are female, study doctors checked again to see if you were pregnant. Of the 300 participants, 241 participants got the 1-strain vaccine, and 59 participants got the placebo.

After treatment was over, researchers checked how you were feeling for about 180 days, or 6 months, after getting the 1-strain vaccine or the placebo. They called you to ask how you were feeling, if you took any new medicines, and if you developed any new diseases.

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 and doctors look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with the 1-strain vaccine are not currently planned.

Did more participants who got the 1-strain vaccine have a fever in the first 7 days after getting the vaccine compared to participants who got the placebo?

No. Researchers counted how many participants reported having a fever. Researchers used degrees Fahrenheit, or °F, to measure participants' temperatures.

Researchers counted the number of participants who reported having a fever of 101°F or higher in the first 7 days after getting the 1-strain vaccine or the placebo. They found the following:

- **1-strain vaccine:** 1 of 241 participants (0.4%) who got the 1-strain vaccine reported a fever of at least 101°F or higher in the first 7 days of getting treatment.
- **Placebo:** 1 of 59 participants (1.7%) who got the placebo reported a fever of at least 101°F or higher in the first 7 days of getting treatment.

Did more participants who got the 1-strain vaccine have certain symptoms in the first 7 and the first 14 days compared to participants who got the placebo?

No. Researchers also counted the number of participants who reported certain symptoms that researchers expected might occur in the first 7 and first 14 days after getting the 1-strain vaccine or the placebo. These symptoms included headache, runny nose, sore throat, tiredness, cough, muscle aches, chills, and vomiting. The tables below show how many participants had these symptoms in the first 7 and first 14 days after getting the 1-strain vaccine or the placebo.

Symptoms in the first 7 days

Symptom	1-strain vaccine (Out of 241 participants)	Placebo (Out of 59 participants)
Headache	32 (13.3%)	13 (22.0%)
Runny nose	31 (12.9%)	10 (16.9%)
Sore throat	15 (6.2%)	8 (13.6%)
Tiredness	11 (4.6%)	4 (6.8%)
Cough	6 (2.5%)	5 (8.5%)
Muscle aches	4 (1.7%)	3 (5.1%)
Chills	3 (1.2%)	2 (3.4%)
Vomiting	0 (0.0%)	0 (0.0%)

Symptoms in the first 14 days

Symptom	1-strain vaccine (Out of 241 participants)	Placebo (Out of 59 participants)
Headache	39 (16.2%)	14 (23.7%)
Runny nose	34 (14.1%)	11 (18.6%)
Sore throat	18 (7.5%)	9 (15.3%)
Tiredness	12 (5.0%)	4 (6.8%)
Cough	8 (3.3%)	5 (8.5%)
Muscle aches	6 (2.5%)	3 (5.1%)
Chills	3 (1.2%)	2 (3.4%)
Vomiting	1 (0.4%)	0 (0.0%)

What medical problems did participants have?

A lot of research is needed to know whether a drug causes a medical problem. 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 during the study?

A slightly higher number of participants who got the 1-strain vaccine had medical problems during the study compared to the number of participants who got the placebo. No participants stopped taking the drug because of a medical problem.

The table below shows how many participants developed medical problems in the first 7 days and first 14 days of the study.

Medical problems in the first 7 and first 14 days

	1-strain vaccine (Out of 241 participants)	Placebo (Out of 59 participants)
How many participants developed medical problems in the first 7 days of the study?	9 (3.7%)	1 (1.7%)
How many participants developed medical problems in the first 14 days of the study?	14 (5.8%)	1 (1.7%)

How many participants had serious medical problems?

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

In this study, no participants developed serious medical problems. No participants died in the study, and no new safety concerns were raised.

What were the most common medical problems in the study that were not considered serious?

Stuffy nose was the most common medical problem that participants developed in this study that was not considered serious.

Researchers thought that 13 out of the 18 non-serious medical problems (72.2%) that happened in the first 14 days after getting treatment were related to the study drug.

The tables below show how many participants developed medical problems that were not considered serious that happened in the first 7 days and first 14 days after getting treatment.

Medical problems that were not considered serious in the first 7 days of the study		
Medical problem	**1-strain vaccine (Out of 241 participants)**	**Placebo (Out of 59 participants)**
Stuffy nose	3 (1.2%)	0 (0.0%)
Nausea	2 (0.8%)	0 (0.0%)
Sneezing	2 (0.8%)	0 (0.0%)
Fever	1 (0.4%)	1 (1.7%)
Bad taste in the mouth	1 (0.4%)	0 (0.0%)
Inflammation of the back of the throat	1 (0.4%)	0 (0.0%)
Inflammation of the voice box	1 (0.4%)	0 (0.0%)

Medical problems that were not considered serious in the first 14 days of the study		
Medical problem	**1-strain vaccine (Out of 241 participants)**	**Placebo (Out of 59 participants)**
Stuffy nose	5 (2.1%)	0 (0.0%)
Nausea	3 (1.2%)	0 (0.0%)
Sneezing	2 (0.8%)	0 (0.0%)
Fever	1 (0.4%)	1 (1.7%)
Bad taste in the mouth	1 (0.4%)	0 (0.0%)
Diarrhea	1 (0.4%)	0 (0.0%)
Food poisoning	1 (0.4%)	0 (0.0%)
Inflammation of the back of the throat	1 (0.4%)	0 (0.0%)
Inflammation of the voice box	1 (0.4%)	0 (0.0%)

Where can I learn more about the 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/NCT02743117.

Official study title: A Phase 4, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety of 1 New 6:2 Influenza Virus Reassortant 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.