# Clinical Study Results

MedImmune
A member of the AstraZeneca Group

**Research Sponsor:** MedImmune, LLC

**Drug Studied:** MEDI7510

**National Clinical Trial #:** NCT02508194

**Eudra CT #:** 2015-002758-11

**Protocol #:** D4420C00005

**Study Date:** September 2015 to November 2016

**Short Study Title:** A study to investigate a new vaccine for the potential prevention of respiratory syncytial virus (RSV) disease in adults 60 years of age and older

## *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 this clinical study for the vaccine MEDI7510. Researchers were developing this vaccine to prevent illness caused by respiratory syncytial virus, also called RSV. This virus causes an illness similar to the flu in people of all ages. You and all of the other participants helped the researchers learn if MEDI7510 was effective in preventing illness caused by RSV, and if it caused any medical problems.

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 doctors or staff at your study site.

## What's happened since this study ended?

This study started in September 2015 and ended in November 2016. It included 1894 participants at 60 study sites in Canada, Chile, Estonia, Latvia, Lithuania, South Africa, and the United States.

When this 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 patients can get a new vaccine, the company developing the vaccine must do research studies to show that it is safe and effective.

The study vaccine, MEDI7510, was being developed to prevent illness caused by respiratory syncytial virus, also called RSV. This virus can cause lung infections. The symptoms of RSV are usually mild, like a common cold, but they can be severe in infants and older adults.

In this study, the researchers wanted to learn if MEDI7510 is effective at preventing illness caused by RSV, and if MEDI7510 causes any medical problems.

The researchers in this study compared an injected dose of MEDI7510 to an injected dose of a placebo. A placebo looks like a vaccine but does not contain any real medicine. Researchers use a placebo to compare the results for participants who get study vaccines with the results for participants who get no vaccine at all. In this study, the placebo was just an injection of salt water.

The researchers in this study wanted to know:

- How effective was the vaccine in preventing diseases caused by RSV?
- How did the participants' immune systems respond to MEDI7510?
- What medical problems did the participants have?

## What kind of study was this?

This study was a "double-blind" study. This means that none of the participants, doctors, or staff knew what treatment each participant got. Some studies are done this way because knowing what treatment each participant gets can affect the results of the study.

This study included 1894 participants. All of the participants were 60 years of age or older.

## What happened during this study?

The participants in this study were located in 1 of 2 world locations:

- The northern hemisphere – The half of the earth north of the equator. The equator is an imaginary line around the middle of the earth.
- The southern hemisphere – The half of the earth south of the equator.

The researchers chose participants in these 2 locations because RSV causes infections mostly during the autumn and winter. These seasons happen at different times in the 2 hemispheres. The researchers wanted to learn how the study drug worked in both places.

The participants in the northern hemisphere were in this study for up to about 11 months.

The participants in the southern hemisphere were in this study for up to about 8 months.

Some of the participants left this study before it was completed.

**To see if the participants could join this study,** the doctors did a physical examination, including checking the height, weight, and the oxygen level in the blood of the participants. The doctors also asked about the medical history of the participants, how they were feeling, and what medicines they were taking.

**During this study,** there were 2 treatments given once during the second visit:

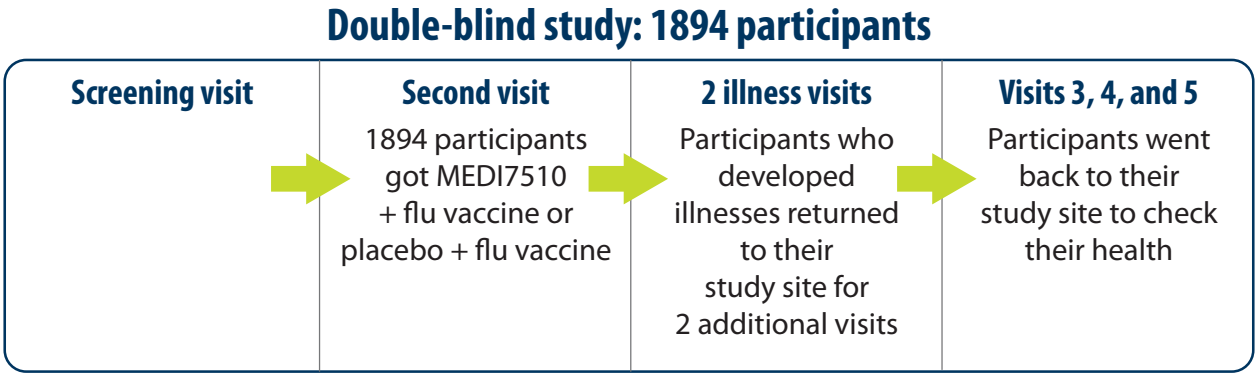
- 946 participants got a MEDI7510 injection and a flu vaccine injection
- 948 participants got a placebo injection and a flu vaccine injection

The participants went back to their study site 3 more times after the second visit. The participants who developed a respiratory illness went back approximately twice for each illness.

Throughout this study, the doctors continued to check the overall health of the participants and ask how they were feeling. Once a month, the doctors also called the participants to ask questions about their health.

After this study ended, the doctors called the participants to tell them whether they had gotten MEDI7510 or the placebo, and to ask the participants about their health again.

The figure below shows how this 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.

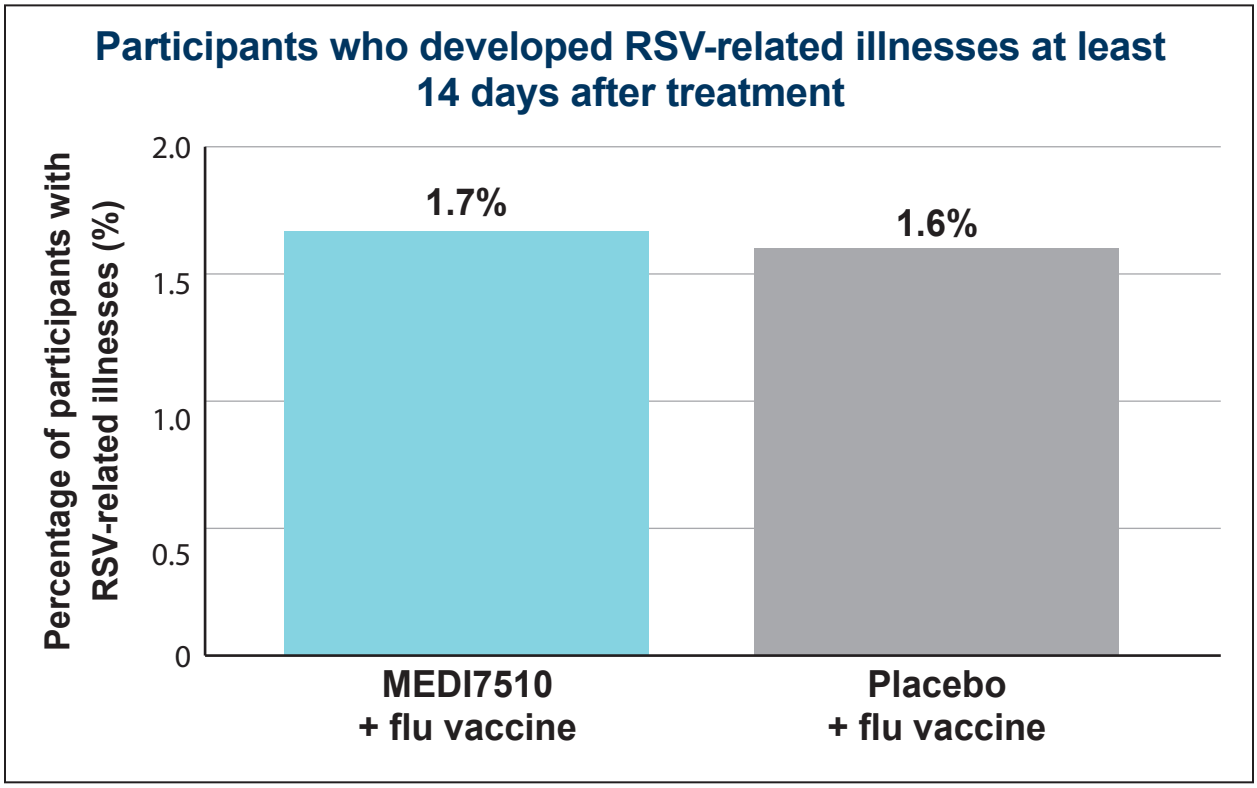
Further clinical studies with MEDI7510 are not planned.

**How effective was the vaccine in preventing diseases caused by RSV?**
The researchers wanted to learn if the participants developed illnesses related to RSV. At least 14 days after the participants got their treatment, the researchers found that:

- 16 out of 931 participants (1.7%) who got MEDI7510 and the flu vaccine developed an illness that was thought to be related to RSV.
- 15 out of 935 participants (1.6%) who got the placebo and the flu vaccine developed an illness that was thought to be related to RSV.

The total number of participants above is less than the total number of participants who started this study. This is because some participants did not finish this study.

The figure below shows how many people got sick at least 14 days after treatment.




**How did the participants' immune systems respond to MEDI7510?**

The researchers also wanted to learn how the participants' immune systems responded to MEDI7510. So, the researchers took blood samples:

- before vaccination
- about 1 month after vaccination
- during the last study visit

The researchers also took blood samples on about Day 4 and Day 22 if the participants had a respiratory illness.

Some of the participants gave additional blood about 1 week after dosing. These blood samples were used to study the body's immune response to the vaccine.

The researchers learned that the vaccine did cause an immune response in the body of most of the participants who were in this study. But, that immune response did not protect them from illness.

# What medical problems did the participants have?

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

The medical problems listed below happened up to and including Day 29 of this study. Day 29 was the fourth visit during this study.

**How many participants developed medical problems during this study?**
By Day 29 of this study, 287 out of 1894 participants (15.2%) developed medical problems. The table below shows the number of medical problems that occurred by Day 29 of this study.

| | MEDI7510 and flu vaccine (out of 946 participants) | Placebo and flu vaccine (out of 948 participants) |
|---|---|---|
| How many participants developed medical problems by Day 29? | 146 (15.4%) | 141 (14.9%) |

**How many participants developed serious medical problems?**
A medical problem is considered serious when it is life-threatening, causes lasting problems, or needs hospitalization.

By Day 29 of this study:

- 4 out of 946 participants (0.4%) who got MEDI7510 and the flu vaccine developed serious medical problems
- 3 out of 948 participants (0.3%) who got the placebo and the flu vaccine developed serious medical problems

At the end of this study:

- 3 out of 946 participants (0.3%) who got MEDI7510 and the flu vaccine died
- 5 out of 948 participants (0.5%) who got the placebo and the flu vaccine died

The researchers did not think that any of the serious medical problems or deaths in this study were related to the study treatments.

## What were the medical problems in this study that were not considered serious?

The table below shows the non-serious medical problems that happened in at least 4 participants in either treatment group by Day 29 of this study.

| Most common medical problems by Day 29 | MEDI7510 and flu vaccine (out of 946 participants) | Placebo and flu vaccine (out of 948 participants) |
|---|---|---|
| Pain at injection area | 10 (1.1%) | 18 (1.9%) |
| Tiredness | 16 (1.7%) | 11 (1.2%) |
| Infection of the nose, throat, and airways | 16 (1.7%) | 10 (1.1%) |
| Viral infection of the nose, throat, and airways | 13 (1.4%) | 10 (1.1%) |
| Headache | 10 (1.1%) | 13 (1.4%) |
| Muscle pain | 7 (0.7%) | 6 (0.6%) |
| Common cold | 6 (0.6%) | 7 (0.7%) |
| Urinary tract infection | 3 (0.3%) | 8 (0.8%) |
| Redness at injection area | 6 (0.6%) | 2 (0.2%) |
| Back pain | 4 (0.4%) | 1 (0.1%) |

## Where can I learn more about this study?

If you have questions about the study results, please speak with the doctors or staff at your study site. You can find more information about this study online at:

- www.clinicaltrials.gov/show/results/NCT02508194
- www.clinicaltrialsregister.eu/D4420C00005

Official study title: A Phase 2b Randomized, Double-blind Study to Evaluate the Efficacy of MEDI7510 for the Prevention of Acute Respiratory Syncytial Virus-associated Respiratory Illness in Older 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 study. 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.

CISCRP
One Liberty Square, Suite 510 • Boston, MA 02109
1-877-MED-HERO • www.ciscrp.org