

Research Sponsor: MedImmune, LLC

Drug Studied: MEDI7734

Study Title: A study to learn more about if MEDI7734 is safe to take for people with immune system diseases

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug MEDI7734.

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 for you.

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?

This study started in August 2016 and ended in November 2017. It included 36 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?

Researchers are looking for a better way to treat immune system diseases. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

Immune system diseases happen when certain types of immune system cells attack healthy cells in the body. This can lead to health problems. The study drug, MEDI7734, is being developed to treat these diseases. MEDI7734 may help reduce these types of immune system cells in the body.

The main question the researchers wanted to answer in this study was:

- What medical problems did the participants have during the study?

The answer to this question is important to know before other studies can be done that help find out if MEDI7734 improves the health of people with immune system diseases. The researchers asked for the help of men and women with certain types of immune system diseases. Everyone in the study was between 31 and 63 years of age when they joined.

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 participants got so they could create a report of the study results.

The participants in this study got either MEDI7734 or a placebo by an injection under the skin. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who get the drug are actually caused by the drug.

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

What happened during the study?

Before the study started, the doctors:

- did a physical examination
- checked the heart health of the participants using an electrocardiogram, also known as an ECG
- took blood and urine samples
- asked about the medical history of the participants, how they were feeling, and what medicines they were taking

At the start of the study, the participants visited their study site once to get the study drug. During this visit, the participants got 1 injection of either:

- MEDI7734, in 1 of 5 different doses
- a placebo

During the study, the participants visited their study site up to 7 more times for follow-up examinations. During these visits, the doctors checked the health of the participants again and asked how they were feeling and what medications they were taking.

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.

What medical problems did the participants have during the study?

The medical problems the participants had in this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities.

The medical problems that participants have during clinical studies that the doctors think might be related to the study drug are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study may or may not be caused by the study drug. A lot of research is needed to know whether a drug causes an adverse reaction.

The websites listed at the end of this summary may have other information about adverse reactions or other medical problems that happened in this study.

How has this study helped patients and researchers?

These results helped the researchers learn more about MEDI7734 and if it is safe to take for people with immune system diseases.

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 1 study. Other studies may provide new information or different results.

Further clinical studies with MEDI7734 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 “**NCT02780674**” into the search box and click “**Search**”.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type “**D6080C00001**” into the search box and click “**Find a Study**”.

Full Trial Title: A Phase 1, Randomized, Blinded, Single-Dose, Dose Escalation Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of MEDI7734 in Type I Interferon-Mediated Autoimmune Diseases

AstraZeneca Protocol Number: D6080C00001

MedImmune, LLC, a member of the AstraZeneca Group of companies, sponsored this study and has its headquarters at 1800 Concord Pike, Wilmington, DE 19850.

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.



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 patients for clinical studies, nor is it involved in conducting clinical studies.

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