Clinical Trial Results

MedImmune
A member of the AstraZeneca Group

Research Sponsor: MedImmune, Ltd
Drugs Studied: MEDI9929 (Tezepelumab)
National Clinical Trial #: NCT02525094
Eudra Clinical Trial #: 2015-000595-10
Protocol #: D5240C00001
Study Date: August 2015 to July 2016
Short Study Title: A study in participants to see if MEDI9929 helps people with atopic dermatitis and if MEDI9929 is safe to take

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 drug called MEDI9929, also known as tezepelumab. This drug is being developed to treat a certain type of skin condition called atopic dermatitis, or AD. You and all of the other participants helped researchers learn if MEDI9929 helps people with AD and if MEDI9929 is safe to take.

MedImmune, Ltd, 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 support 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 August 2015 and ended in July 2016. It included 113 participants at 26 study sites in Australia, Canada, Germany, Hungary, New Zealand, and 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 study drug, MEDI9929, is being developed to treat atopic dermatitis, or AD. AD, also known as eczema, is a skin disease that can cause itchy, red, swollen, and cracked skin. Currently, there is no cure for AD. Prescription drugs can relieve the symptoms of AD but cannot cure AD.

Another treatment for AD is skin creams that contains steroids. But, these creams do not always treat the symptoms of AD in patients. These creams can also cause side effects like blotchy skin, increased risk of skin infections, and weaker bones.

Researchers have found that people with AD have higher levels of a protein called thymic stromal lymphopoietin, or TSLP. The study drug, MEDI9929, is a type of antibody that blocks TSLP. In the body, antibodies are normally made by the immune system to fight off infection.

Researchers can use antibodies as medications to treat different diseases, including AD. In this study, researchers compared MEDI9929 to a placebo. A placebo looks like the study drug but contains no real medicine in it. Researchers use a placebo in some studies so that they can compare the results of participants who take study drugs to the results of participants who take no medicine at all.

Researchers wanted to know:

- Did participants who got MEDI9929 have less severe AD after 12 weeks of treatment than participants who got a placebo?
- How did MEDI9929 act in the body?
- Did the immune system of participants make antibodies against MEDI9929 in the blood?
- What medical problems did participants have after getting MEDI9929?

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 can affect the results of the study. This way, the results are looked at fairly.

In this study, participants got either MEDI9929 or the placebo.

Your study included men and women with moderate or severe AD who were 18 to 71 years old.

What happened during the study?

You and other participants were in the study for about 6 months.

To see if you could join the study, study doctors did a physical examination by checking your height, weight, and temperature. Study doctors took blood and urine samples and checked your heart health using an electrocardiogram, or ECG. Study doctors also checked your skin for AD symptoms and asked about your medical history, how you were feeling, and what medicines you were taking.

If you are female, you had a blood test to make sure you were not pregnant.

Before and during the study, study doctors used a scoring system to look at how severe participants' AD symptoms were. A higher score meant the AD symptoms were more severe.

Once you joined the study, you began using a steroid cream on your skin for 2 weeks. After 2 weeks, you were randomly assigned to get either MEDI9929 or the placebo. All participants in the trial had the same chance of getting the study drug or the placebo.

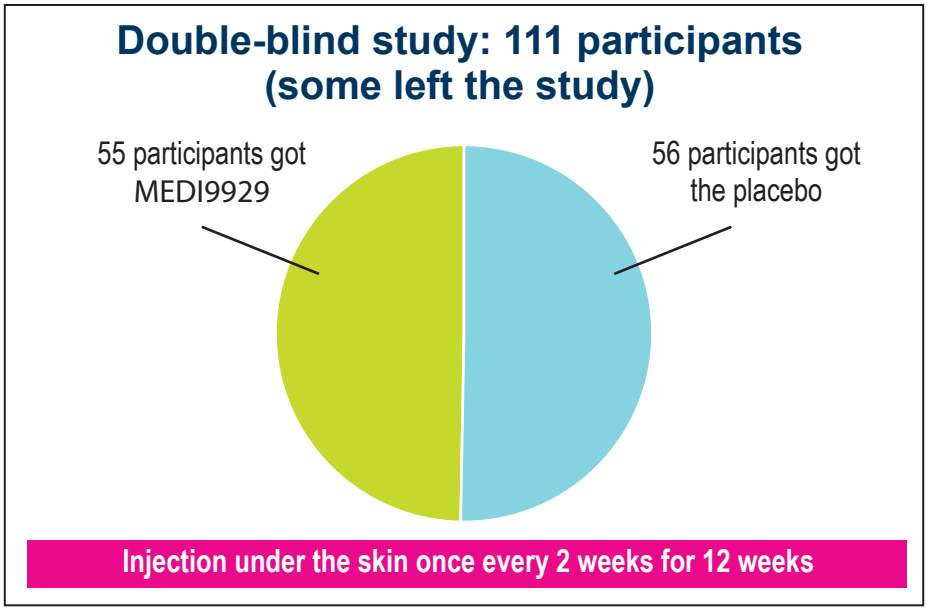
Out of the original 113 participants, 111 participants got treatment - 55 got MEDI9929 and 56 got the placebo. Some participants left the study before it was completed.

MEDI9929 or the placebo was injected under the skin every 2 weeks for a total of 10 weeks. In addition to MEDI9929 or the placebo, all participants continued to use the steroid cream on their skin throughout the study.

During the study, study doctors did a physical examination by checking your height, weight, and temperature again. Study doctors took more blood and urine samples and checked your heart health using an ECG. Study doctors also checked your skin for AD symptoms and asked about your medical history, how you were feeling, and what medicines you were taking. Study doctors checked how you were feeling 6 weeks and then 12 weeks after your last treatment. They asked you what other medicines you were taking, if you had any new medical problems, and what your symptoms were like.

During the follow-up period, study doctors used the same scoring system to look at how severe participants' AD symptoms were. This period lasted 22 weeks. Study doctors asked if you had any new medical problems and what your symptoms were like.

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 MEDI9929 are not planned in 2017.

The results below were analyzed for 55 of the participants in the MEDI9929 group and 56 of the participants in the placebo group. This is because 2 of the participants did not get any treatment in the study.

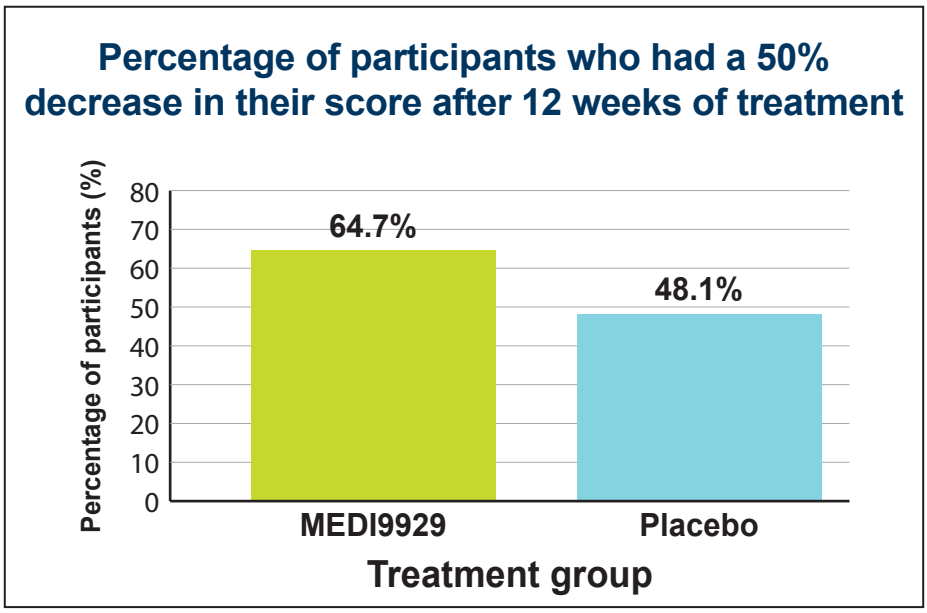
Did participants who got MEDI9929 have less severe AD after 12 weeks of treatment than participants who got a placebo?

To answer this question, study doctors used a scoring system to look at how severe participants' AD symptoms were. A higher score meant the AD symptoms were more severe.

Researchers counted the number of participants who had at least a 50% decrease in their score from before treatment to after treatment. Researchers measured these results for 51 participants who got MEDI9929 and 54 participants who got the placebo.

They found that 33 of the 51 participants (64.7%) who got MEDI9929 had at least a 50% decrease in their score compared to 26 of the 54 participants (48.1%) who got the placebo. Overall, researchers found that the difference between the treatment groups was too small for researchers to know if one treatment was better than the other.

The graph below shows the percentage of participants in each treatment group who had at least a 50% decrease in their score after 12 weeks of treatment.



How did MEDI9929 act in the body?

Researchers measured the amount of MEDI9929 in the blood of participants.

Overall, they found that the amount of MEDI9929 increased in the blood of participants after 10 weeks of getting the study drug. This treatment period lasted 12 weeks.

Did the immune system of participants make antibodies against MEDI9929 in the blood?
Researchers also wanted to see if the immune system of participants made antibodies against MEDI9929 in the blood. If antibodies form against MEDI9929, the drug may not work as well or it may cause an allergic reaction to the drug. One or both of these reactions could happen, or neither of these reactions could happen.

Researchers found that no participants in this study formed antibodies against MEDI9929 after treatment.

What medical problems did participants have during the study?

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.

The results below were analyzed for 56 of the participants in the MEDI9929 group and 55 of the participants in the placebo group.

How many participants had medical problems in the study?
In this study, a similar number of participants in both the MEDI9929 and the placebo groups had medical problems. The table below shows how many participants had medical problems during the study.

	MEDI9929 (Out of 56 participants)	Placebo (Out of 55 participants)
How many participants had medical problems?	38 (67.9%)	40 (72.7%)
How many participants had serious medical problems?	2 (3.6%)	3 (5.5%)
How many participants stopped treatment because of medical problems?	2 (3.6%)	4 (7.3%)

How many participants had serious medical problems in the study?
A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospitalization.

No participants died during this study.

Two participants (3.6%) who got MEDI9929 and 3 participants (5.5%) who got the placebo had serious medical problems in this study. The only serious medical problem that happened in more than 1 participant, no matter which treatment they got, was a serious worsening of AD, as shown in the table below.

The table below shows the serious medical problems that happened in this study.

Serious medical problem	MEDI9929 (Out of 56 participants)	Placebo (Out of 55 participants)
Worsening of AD	1 (1.8%)	1 (1.8%)
Infected bump under the skin	1 (1.8%)	0 (0.0%)
Bacterial skin infection	0 (0.0%)	1 (1.8%)
Chest pain	0 (0.0%)	1 (1.8%)
Fainting	0 (0.0%)	1 (1.8%)

What were the most common non-serious medical problems in the study?

The common cold was the most common non-serious medical problem in either treatment group. The table below shows the most common non-serious medical problems that occurred in at least 5% of participants in this study.

Non-serious medical problem	MEDI9929 (Out of 56 participants)	Placebo (Out of 55 participants)
Common cold	13 (23.2%)	11 (20.0%)
Worsening of AD	6 (10.7%)	7 (12.7%)
Diarrhea	5 (8.9%)	3 (5.5%)
Headache	3 (5.4%)	1 (1.8%)
Redness of the skin at the injection site	3 (5.4%)	0 (0.0%)
Infection of nose, throat, and/or sinus	1 (1.8%)	7 (12.7%)
Bacterial skin infection	0 (0.0%)	3 (5.5%)

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/NCT02525094.

Official study title: A Phase 2a, Randomized, Double-blinded, Placebo-controlled Study to Evaluate the Efficacy and Safety of MEDI9929 in Adult Subjects with Moderate-to Severe Atopic Dermatitis

MedImmune, Ltd, the sponsor of this study, is a member of the AstraZeneca Group of companies which 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.