Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca

Drug Studied: AZD0284

Study Title: A study to learn how AZD0284 acts in the body, and if AZD0284 is safe to take for participants with plaque psoriasis

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Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD0284. AstraZeneca 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.

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?

The study started in November 2017 and ended in November 2018. The study included 9 participants.

The researchers planned to include 25 participants in this study. But they ended the study early, because at that time, they decided to stop researching AZD0284 in participants who have plaque psoriasis.

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 people who have plaque psoriasis. 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.

Plaque psoriasis is a disease that happens when a person's immune system does not work as well as it should. In healthy people, the immune system fights infections or anything it does not recognize by creating certain proteins. These include proteins called IL-17A and CCL20, which cause swelling.

In people who have psoriasis, the body creates too many of these proteins. This can cause a higher than normal amount of swelling, which can cause the immune system to attack healthy tissue. This can cause several medical problems, including red, itchy, scaly patches called "plaques" to form on the skin.

The study drug, AZD0284, was developed to treat plaque psoriasis by decreasing the amounts of proteins that cause a higher than normal amount of swelling. This decrease might help the immune system to attack only infections and not healthy tissue.

In this study, the researchers wanted to find out if AZD0284 helped decrease the amount of IL-17A and CCL20 in the body. They also wanted to learn if AZD0284 helped decrease the severity of the participants' skin plaques and their itching, and if AZD0284 caused any medical problems.

The main questions the researchers wanted to answer in this study were:

- Did AZD0284 help decrease the severity of participants' skin plaques?
- Did AZD0284 help decrease the amounts of IL-17A and CCL20 in the body?
- Did AZD0284 help decrease the itchiness of the participants' skin plaques?
- What medical problems did the participants have during the study?

What kind of study was this?

This was a “double-blind” study. This means none of the participants or researchers knew which treatment the participants took. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. When the study ended, the research sponsor found out which treatment each participant took so they could create a report of the study results.

In this study, the participants took either AZD0284 or a placebo as a liquid by mouth. 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 take the drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant took. 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 taking any study treatment, the participants visited their study site 1 time over the course of 2 weeks. At this visit, the study doctors checked to make sure the participants could join the study. The study doctors:

- did a physical examination
- took blood and urine samples
- checked the participants’ heart health using an electrocardiogram, also called an ECG
- took samples of the participants’ skin plaques
- gave the participants surveys that asked them how itchy their skin plaques were
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

Throughout the study, the study doctors continued checking the participants’ overall health, taking samples of their skin plaques, and giving them surveys asking how itchy their skin plaques were.

During the study, the participants visited their study site 5 times over the course of about 4 weeks. During this time, the participants took either AZD0284 or the placebo 2 times each day.

After taking their last treatment, the participants visited their study site up to 2 times over the course of 4 weeks. At these visits, the study doctors checked the participants' overall health, took samples of their skin plaques, and gave them surveys asking how itchy their skin plaques were.

What were the results of the study?

This is a summary of the main results from this study. 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.

Did AZD0284 help decrease the severity of the participants' skin plaques?

Because of the small number of participants in the study, the researchers could not determine if AZD0284 helped decrease the severity of the skin plaques.

To answer this question, the study doctors used a measurement called the Psoriasis Area and Severity Index, also called PASI. The study doctors used the PASI to give each participant a score based on:

- the redness of their skin plaques
- the thickness of their skin plaques
- the amount of skin peeling around their skin plaques

The study doctors gave the participants scores before they took treatment and after 4 weeks of taking treatment. The higher the scores, the more severe the psoriasis symptoms were. The researchers compared the scores of the participants who took AZD0284 with the scores of the participants who took the placebo.

Did AZD0284 help decrease the amounts of IL-17A and CCL20 in the body?

Because of the small number of participants in the study, the researchers could not determine if AZD0284 helped decrease the amounts of these proteins.

To answer this question, the study doctors took samples of the participants' skin plaques before they took treatment and after 4 weeks of taking treatment. The researchers compared the amounts of IL-17A and CCL20 in the samples of the participants who took AZD0284 with the amounts of IL-17A and CCL20 in the samples of the participants who took the placebo.

Did AZD0284 help decrease the itchiness of the participants' skin plaques?

Because of the small number of participants in the study, the researchers could not determine if AZD0284 helped decrease the itchiness of the participants' skin plaques.

To answer this question, the researchers gave the participants a survey called the Pruritus Visual Analogue Score, also called pVAS. This survey asked the participants to rate how itchy their skin plaques were. Based on the rating, the study doctors gave the participants a score from 0 to 10. The higher the score, the more severe the itchiness was. The researchers compared the results of the pVAS before the participants took treatment and after 4 weeks of taking treatment. They compared the scores of the participants who took AZD0284 with the scores of the participants who took the placebo.

What medical problems did the participants have during the study?

The medical problems that the participants had during 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 a study 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. In this study, there were no serious adverse reactions.

How has this study helped patients and researchers?

This study ended early and there were a small number of participants. So, the researchers did not have enough information to make any conclusions about how AZD0284 affected the participants.

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

Further clinical studies with AZD0284 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 **"NCT03310320"** into the search box, and click **"Search"**.
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home and Search"**, then type **"2017-002351-29"** in the search box, and click **"Search".**
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D7800C00003"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Randomised, Double-Blind, Placebo-Controlled, Parallel Arm, Multi-Center, Phase 1b Study to Assess Pharmacodynamics, Efficacy and Safety of One Dose Level of Oral AZD0284 Given Twice Daily for Four Weeks, Compared to Placebo, in Patients with Moderate to Severe Plaque Psoriasis

AstraZeneca Protocol Number: D7800C00003

AstraZeneca sponsored this study and has its headquarters at 1800 Concord Pike in Wilmington, Delaware.

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 patients.

CISCRP

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 studies, nor is it involved in conducting clinical studies.

CISCRP
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