

Clinical Study Results



Research sponsor: AstraZeneca AB

Drug studied: AZD0284

Short study title: A study to learn if AZD0284 is safe to take for patients with psoriasis

Thank you!

Thank you for taking part in the clinical study for the drug AZD0284. This drug is being developed to treat patients with psoriasis. The study started in December 2016 and ended in May 2017.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study with you and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you. We hope it helps you understand and feel proud of your important role in medical research.

If you participated in the study and have questions about the results, please speak with the doctor or staff at your study site.

Why was the research needed?

Researchers are looking for a better way to treat a skin disease called psoriasis. Psoriasis causes dry and itchy patches of skin on the body. AZD0284 is being developed to treat this disease.

Before a drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is. This information is important to know before other studies can be done to find out if AZD0284 helps treat psoriasis.

In this study, the researchers wanted to find out if the participants had any medical problems during the study.

What kind of study was this?

This was a “single-blind” study. This means the researchers knew what the participants were taking, but the participants did not.

In this study, participants took either AZD0284 or a placebo. 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 the study started, the study doctors did a physical examination to make sure you could join the study. They checked your height, weight, blood pressure, pulse, and temperature. They took blood and urine samples and checked your heart health using an electrocardiogram, also known as an ECG. The study doctors also asked about your medical history, how you were feeling, and what medicines you were taking.

This study had 3 parts: Part 1a, Part 1b, and Part 2. All participants took either AZD0284 or a placebo by mouth in liquid form.

Part 1a

Participants in Part 1a were in the study for up to 6 weeks. They visited their study site 4 times.

Participants in Part 1a took 1 of 7 doses of AZD0284 or a placebo without food. The amount of AZD0284 in each dose was different. The first dose had the lowest amount of AZD0284 and the seventh dose had the highest amount.

About 1 week after their treatment, participants had a follow-up examination.

Part 1b

Participants in Part 1b were in the study for up to 6 weeks. They visited their study site 6 times. Participants in Part 1b took 1 dose of AZD0284 or a placebo with food.

About 1 week after their treatment, participants had a follow-up examination.

Part 2

Participants in Part 2 were in the study for up to 8 weeks. They visited their study site 3 times.

Participants in Part 2 took 3 doses of either AZD0284 or a placebo without food.

About 1 week after their treatment, participants had a follow-up examination.

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 may not be in this summary. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it also can be found on these websites.

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 changes.

What medical problems did participants have after taking AZD0284?

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

How has this study helped patients and researchers?

This study helped researchers learn about the safety of AZD0284 and its ability to help participants with psoriasis.

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 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 also can be found here.

- www.clinicaltrials.gov. Once you are on the website, type “**NCT02976831**” into the search box and click “**Search**”.
- www.clinicaltrialsregister.eu. Once you are on the website, click “**Home & Search**”, then type “**2016-003305-34**” in the search box and click “**Search**”.

The full title of your study is: A Phase I Randomized Single-Blind, Placebo- Controlled 2-Part Study to Assess the Safety, Tolerability and Pharmacokinetics and Pharmacodynamics of AZD0284 Following Single and Multiple Ascending Dose Administration to Healthy Subjects

The protocol number of your study is: D7800C00001

AstraZeneca AB sponsored this study and has headquarters in Södertälje, Sweden.

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

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