Clinical Study Results

AstraZeneca

Research sponsor: AstraZeneca AB

Drug studied: AZD4831

Study title: A study in healthy male participants to learn if AZD4831 is safe to take

Thank you!

Thank you for taking part in the clinical study for the study drug AZD4831.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study. 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 May 2017 and ended in November 2017.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

The study included 38 participants in the United States. But, 1 participant decided to leave the study early before taking any study drug.

Why was the research needed?

Researchers are looking for a better way to treat heart 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.

The researchers wanted to find out if the participants had any medical problems during this study. This information is important to know before other studies can be done that will help find out if AZD4831 improves the health of people with heart disease.

Heart disease can happen when the body produces too much of a specific type of protein. The study drug, AZD4831, may be able to help reduce the levels of this protein in the body. Having a lower level of this protein may help improve the health of patients with heart disease.

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

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

The researchers asked for the help of healthy male participants. Everyone in the study was between 23 and 50 years old when they joined.

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.

There were 4 groups in the study. The participants in each group were assigned to take either AZD4831 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.

Each group was given a different dose of AZD4831:

- Group 1 took the lowest dose.
- Group 2 took a high dose.
- Group 3 took the highest dose.
- Group 4 took a low dose. This dose was higher than the Group 1 dose but lower than the Group 2 dose.

All of the treatments were taken in liquid form by mouth:

- Participants in Group 1 and Group 2 took AZD4831 or a placebo once a day for 10 days.
- Participants in Group 3 were supposed to take AZD4831 or a placebo once a day for 10 days.
- Participants in Group 4 took AZD4831 or a placebo once a day for 14 days.

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 doctors did a physical examination to make sure the participants could join the study. They checked the heart health of the participants using an electrocardiogram, also known as an ECG. The doctors also asked about the medical history of the participants, how they were feeling, and what medicines they were taking.

The participants checked in at the study site 1 day before the study started and stayed overnight.

During the study, the participants stayed at the study site overnight for the entire treatment visit. Each participant took his treatment once a day during this treatment visit.

Treatment lasted 10 days for the first 2 groups.

The researchers ended the treatment early for Group 3. One of the participants in this group had a medical problem. For safety reasons, the researchers decided to stop treatment for the whole group.

To find a dose that causes fewer medical problems, the researchers started Group 4, and the treatment in this group lasted for 14 days. This group took a low dose that was higher than the Group 1 dose but lower than the Group 2 dose.

During these visits, the study doctors took blood and urine samples. They checked the heart health of the participants using an ECG. They also asked how the participants were feeling and what medicines they were taking.

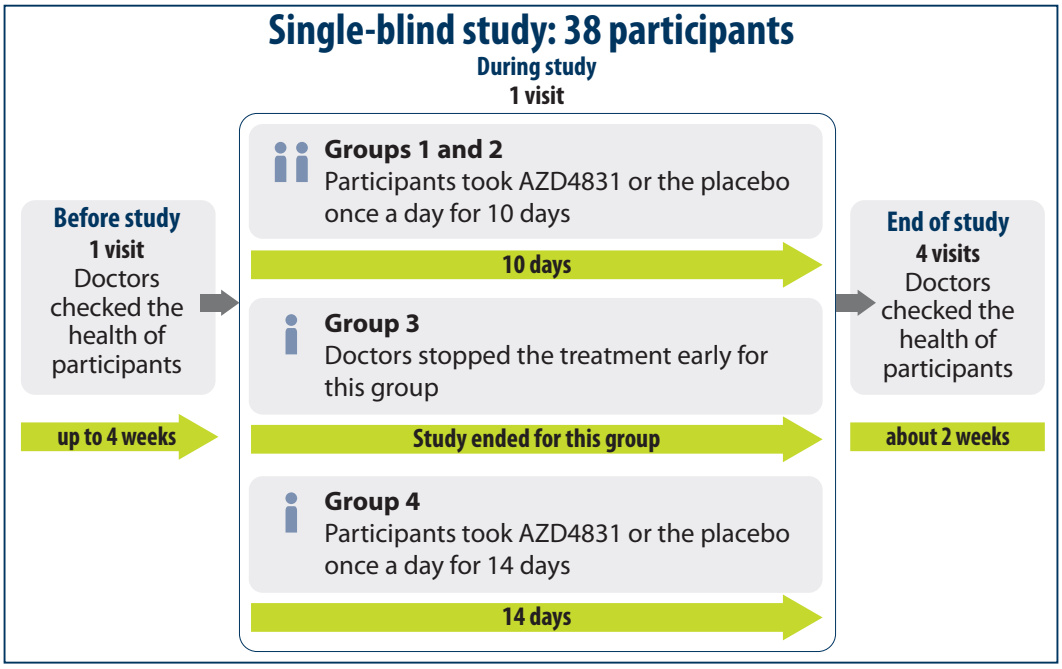
Participants in each group took either AZD4831 or the placebo:

- 2 participants took the placebo and 8 participants took the lowest dose of AZD4831 in Group 1.
- 2 participants took the placebo and 8 participants took the high dose of AZD4831 in Group 2.
- 2 participants took the placebo and 5 participants took the highest dose of AZD4831 in Group 3.
- 2 participants took the placebo and 8 participants took the low dose of AZD4831 in Group 4.

Participants left the study site 2 days after their last dose.

At the end of the study, the participants visited their study site 4 more times for follow-up visits over the course of about 2 weeks. During these visits, the doctors checked the health of the participants again. The doctors asked how the participants were feeling and what medicines they were taking.

The graphic below shows how the study was done.



What were the results of the study?

This is a summary of the main results from the 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 website listed at the end of this summary may have a full report of the study results.

What medical problems did participants have during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study drug. These medical problems are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse reactions 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 website listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

The 1 participant who left the study early is not included in the results below because he did not take any study drug.

How many participants had serious adverse reactions?

None of the participants had serious adverse reactions during the study. None of the participants died during the study.

How many participants had adverse reactions?

There were 21.6% of participants who had adverse reactions during the study. This was 8 out of 37 participants.

There were 8.1% of participants who stopped taking AZD4831 because of adverse reactions they had during the study. This was 3 out of 37 participants.

What adverse reactions did the participants have?

The most common adverse reactions were rash, headache, and dry throat. Participants who took the highest AZD4831 dose had more adverse reactions than participants who took the lower AZD4831 doses.

The adverse reactions below happened in 2 or more of the total number of participants. There were other adverse reactions, but these happened in fewer participants. The groups are presented in the order of increasing dose.

Most common adverse reactions during the study

	Group 1 Out of 8 participants who took the lowest dose of AZD4831	Group 4 Out of 8 participants who took the low dose of AZD4831	Group 2 Out of 8 participants who took the high dose of AZD4831	Group 3 Out of 5 participants who took the highest dose of AZD4831
Rash	0.0% (0)	0.0% (0)	25.0% (2)	40.0% (2)
Headache	0.0% (0)	12.5% (1)	0.0% (0)	20.0% (1)
Dry throat	0.0% (0)	0.0% (0)	12.5% (1)	20.0% (1)

How has the study helped patients and researchers?

The results presented here are for a single study in healthy male participants. These results helped the researchers learn about how safe it was to take AZD4831 for participants in the study.

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.

Further clinical studies with AZD4831 are planned.

Where can I learn more about the study?

You can find more information about the study on the website 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 **"NCT03136991"** into the search box and click **"Search"**.

Full study title: A Phase I, Randomized, Single-blind, Placebo-controlled Study to Assess the Safety, Tolerability and Pharmacokinetics of AZD4831 after Multiple Ascending Dose Administration to Healthy Male Subjects

AstraZeneca protocol number: D6580C00004

AstraZeneca AB sponsored this study and has its 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.

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 studies, nor is it involved in conducting clinical studies.

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