AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD4831

Study Purpose: This study was done to learn about the safety of AZD4831 in healthy men of Japanese or Chinese ethnic origin

Protocol Number: D6580C00008

Thank you

Thank you to the participants who took part in the clinical study for the study drug AZD4831.

AstraZeneca AB sponsored this study and believes 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 study doctor or staff at your study site.

Who took part in this study?

The researchers asked for the help of healthy men of Japanese or Chinese ethnic origin who live in the United States. The participants in this study were 22 to 47 years old when they joined.

The study included 32 participants in the United States.

Why was the research needed?

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

When the body makes too much of a protein called myeloperoxidase, also called "MPO", it can sometimes be a factor in causing heart disease.

AZD4831 may be able to help reduce the levels of MPO in the body. Having a lower amount of MPO may help improve the health of people with heart disease.

What was the purpose of this study?

In this study, the researchers wanted to learn about the safety of AZD4831 in healthy men of Japanese and Chinese ethnic origin.

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

- What signs and symptoms did the participants have during the study?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done to find out if AZD4831 improves the health of people who have heart disease.

What treatments did the participants take?

In this study, all of the participants took 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.

This was a "single-blind" study. This means the researchers, study doctors, and other study staff knew what the participants were taking but the participants did not.

A computer program was used to randomly choose whether the participant took AZD4831 or the placebo. 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.

For the Japanese participants, this study was also a "dose escalation" study. This means that the first participants who took AZD4831 got a low dose. The study doctors looked at the results for these participants. Then they decided whether to increase the dose of AZD4831 in the next group of participants who had been randomly chosen to take AZD4831.

The chart below shows the treatments the participants took. The doses of AZD4831 were measured in milligrams, also called "mg".

	Japanese participants				Chinese participants	
	Placebo	2.5 mg of AZD4831	5 mg of AZD4831	10 mg of AZD4831	Placebo	5 mg of AZD4831
	6 participants	6 participants	6 participants	6 participants	2 participants	6 participants
	AZD4831 or the placebo as a liquid by mouth					
	1 dose a day for 10 days					

What happened during this study?

The study started in January 2020 and ended in March 2021.

Before the participants took study treatment, they visited their study site 1 time. There was up to 1 month between this visit and the participants taking the study treatment. At this visit, the study doctors made sure the participants could join the study. They also:

- did physical exams and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also known as an "ECG"

The study doctors also did these tests and measurements throughout the study.

While the participants took study treatment, they stayed at the study site for about 2 weeks. The participants took AZD4831 or the placebo once a day for the first 10 days of their visit.

After the participants took study treatment, they visited their study site 4 times. These visits happened up to 10 days after the last treatment visit. At these visits, the study doctors checked the health of the participants.

What were the results of this 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 changes.

The websites listed at the end of this summary may have more information about the study results.

What signs and symptoms did the participants have during the study?

The study doctors kept track of the "adverse events" that the participants had.

An adverse event is any sign or symptom that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment.

Later in this document, there will be a summary of the adverse events that the study doctors thought might be related to the study treatment. This section is a summary of all the adverse events, whether they might be related to the study treatment or not. An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or the participant needs hospital care.

Adverse events may or may not be caused by the treatments in the study. A lot of research is needed to know whether a treatment causes an adverse event.

How many participants had adverse events?

- 37.5% of the participants who took AZD4831 had adverse events. This was 9 out of 24 participants.
- 12.5% of the participants who took the placebo had an adverse event. This was 1 out of 8 participants.

How many participants had serious adverse events?

- None of the participants had a serious adverse event during the study.

How many participants stopped taking study treatment due to adverse events?

- 20.8% of the participants who took AZD4831 stopped taking study treatment due to adverse events. This was 5 out of 24 participants.
- None of the 8 participants who took the placebo stopped taking it due to adverse events.

Overall, the number of participants who had adverse events was higher in the groups who took the higher doses of AZD4831. The only adverse events that happened in more than 1 participant were:

- skin rash
- itchy, red, and dry skin
- fever

What medical problems happened during this 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for AZD4831.

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

Did any adverse reactions happen during this study?

How many participants had adverse reactions?

- 25.0% of the participants who took AZD4831 had adverse reactions. This was 6 out of 24 participants.
- None of the 8 participants who took the placebo had an adverse reaction.

How many participants had serious adverse reactions?

- None of the participants had a serious adverse reaction or died during the study.

How many participants stopped taking study treatment due to adverse reactions?

- 20.8% of the participants who took AZD4831 stopped taking study treatment due to adverse reactions. This was 5 out of 24 participants.
- None of the 8 participants who took the placebo stopped taking it due to adverse reactions.

The number of participants who had adverse reactions was higher in the groups who took the higher doses of AZD4831. The only adverse reactions that happened in more than 1 participant were **skin rash** and **fever**.

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of AZD4831.

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 AZD4831 are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If more information about the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT04232345"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6580C00008"** into the search box and click **"Find a Study"**.

Full Study Title: A Phase I, Randomized, Placebo-controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AZD4831 following Multiple-ascending Dose Administration in Japanese and Chinese Healthy Volunteers

AstraZeneca AB Protocol Number: D6580C00008

National Clinical Trials Number: NCT04232345

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 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.

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