AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Treatment Studied: AZD4831

Study Purpose: This study was done to learn how AZD4831 passes through, breaks down, and leaves the body in healthy male participants

Protocol Number: D6580C00007

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. The participants in this study were 22 to 39 years old when they joined.

The study included 6 participants in the United Kingdom.

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, it can sometimes be a factor in causing heart disease. Myeloperoxidase is also called "MPO".

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 patients with heart disease.

What was the purpose of this study?

In this study, the researchers wanted to learn how AZD4831 passes through the body, breaks down, and leaves the body.

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

- How much AZD4831 left the participants' bodies in their urine and faeces?
- 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 a radio-labelled form of AZD4831.

"Radio-labelled" means that it had a low amount of radioactivity in it. The radioactivity made it easier for the researchers to look at AZD4831 in the participants' bodies.

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

The dose of AZD4831 was measured in milligrams, also known as "mg".

The participants did not eat for at least 8 hours before taking AZD4831, and did not eat again until about 4 hours after taking AZD4831.

The chart below shows the treatment the participants took.

	AZD4831
	6 participants
	Morning of the second day of their hospital visit
	10 mg as a liquid by mouth
	1 dose taken 1 time

What happened during this study?

The study started in June 2020 and ended in August 2020.

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 a physical exam and asked about the participants' medications and any medical problems they were having
- took blood, urine, and faecal 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 on the morning of their second day at the hospital.

After the participants took study treatment, they visited their study site 1 time. This visit happened up to 10 days after the previous study visit. At this visit, 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.

How much AZD4831 left the participants' bodies in their urine and faeces?

Overall, the researchers found that **83.6% of the dose of AZD4831** had left the participants' bodies in their urine and faeces after 14 days.

To answer this question, the researchers took urine and faeces samples from the participants before and after they took AZD4831. The researchers collected these samples for up to 14 days after the participants took AZD4831.

The researchers measured the total amount of radioactivity in the participants' urine and faeces. They calculated how much AZD4831 the participants had in their bodies after they first took AZD4831. Then, they compared that amount to how much AZD4831 was in their bodies after 14 days. They calculated this difference as a percentage.

What medical problems happened during this study?

The medical problems participants have during clinical studies that the study doctors think might be related to the study drug are called "adverse reactions".

During the study, **none of the participants** had an adverse reaction.

How has this study helped patients and researchers?

This study helped researchers learn more about how AZD4831 breaks down and leaves the body.

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 **"NCT04407091"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6580C00007"** into the search box and click **"Find a Study"**.

Full Study Title: A Phase I, Open-Label, Single-Period Study to Assess the Mass Balance Recovery, Pharmacokinetics, Metabolite Profile and Metabolite Identification after Oral Administration of [14C]AZD4831 in Healthy Male Subjects

AstraZeneca Protocol Number: D6580C00007

National Clinical Trials Number: NCT04407091

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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Version 1.0 2022_05_05