AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD5718

Study Title: A study to learn how AZD5718 acts in the body in healthy male participants

Protocol Number: D7550C00007

Thank you!

Thank you for taking part in the clinical study for the study drug AZD5718.

AstraZeneca AB sponsored this study and believes it is important to share the results. An independent non-profit organisation 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 the study?

The researchers asked for the help of healthy men. The participants in this study were 39 to 58 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.

In people with heart disease, blood vessels that supply the heart with oxygen are narrowed or blocked by the build-up of cholesterol and fats. This can block the flow of blood to the heart. Serious cases of heart disease can cause heart attacks. The study drug, AZD5718, was developed to treat heart disease.

In this study, the participants got a single dose of AZD5718. The researchers wanted to find out how AZD5718 was taken up in the body and how much of it was found in the participants' urine and faeces. Learning how a study drug acts in the body helps researchers decide what dose to give to participants in future studies.

What was the purpose of this study?

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

- How much AZD5718 was found in the participants' urine and faeces?
- How much AZD5718 got into the participants' blood?
- 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 AZD5718 helps improve the health of people with heart disease.

What treatments did the participants take?

In this study, all of the participants took a single dose of AZD5718 as a liquid by mouth. The dose that each participant took had a low amount of radioactivity in it. This made it easier for the researchers to monitor how AZD5718 acted 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 participants stayed overnight at their study site for at least 9 days, and up to 11 days if the study doctors had more tests to do. They took AZD5718 on Day 2 of their stay at the study site.

What happened during the study?

The study started in May 2019 and ended in July 2019.

Before the participants took study treatment, they visited their study site 1 time within a period of 4 weeks. At this visit, the study doctors checked the health of the participants to make sure they could join the study. The study doctors:

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

While the participants stayed at the study site, the study doctors repeated most of the tests and measurements done before the participants took AZD5718. They also took samples of the participants' faeces during the study. The participants took a single dose of radioactive AZD5718 on Day 2 of their stay at the study site.

Day	1	2	3	4	5	6	7	8	9	10	11
AZD5718		X									

Up to 10 days after the participants left the study site, they had 1 phone call with the study doctors. During this call, the study doctors asked about the participants' health and any medications they were taking.

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 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 AZD5718 was found in the participants' urine and faeces?

To answer this question, the researchers took urine and faeces samples from the participants before and after they took AZD5718. The researchers collected these samples for up to 13 days after the participants took the single radioactive dose.

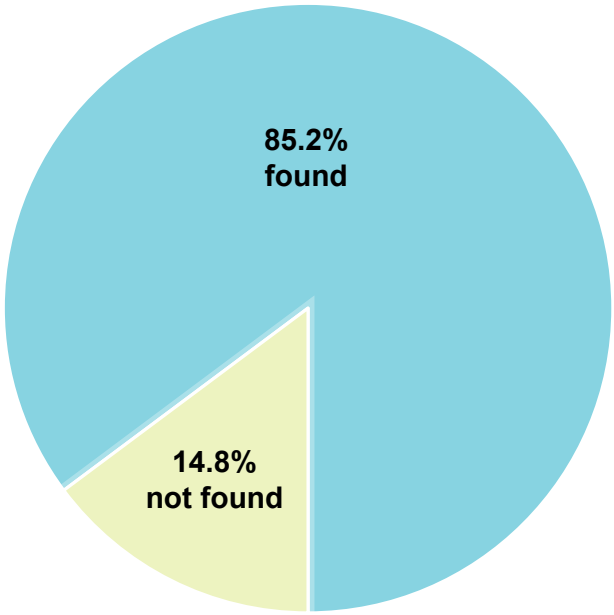
The researchers measured the total amount of radioactivity that was found in the participants' urine and faeces. Then, they calculated the percentage from the original amount of radioactivity that the participants took. This helped them learn how much AZD5718 had been processed and was found in the urine and faeces.

Overall, the researchers found that:

- **85.2%** of the original amount of AZD5718 that the participants took was found in their urine and faeces.

The chart below shows this result:

Percentage of AZD5718 found in urine and faeces



How much AZD5718 got into the participants' blood?

To answer this question, the researchers took blood samples from the participants before and after they took AZD5718. Then, they measured the amount of AZD5718 that got into the participants' blood.

The study doctors measured:

- the average highest amount of AZD5718 in the participants' blood
- the average total amount of AZD5718 in the participants' blood over time

Average highest amount of AZD5718

The average highest amount of AZD5718 was measured in units called nanomoles per litre, also known as nmol/L. The researchers found that:

- The average highest amount of AZD5718 in the blood after taking AZD5718 was **1035 nmol/L**.

Average total amount of AZD5718 over time

The average total amount of AZD5718 over time was measured in units called nmol/L per hour, also known as h per nmol/L. The researchers found that:

- The average total amount of AZD5718 in the blood after the dose of AZD5718 was **5080 h per nmol/L**.

The amounts of AZD5718 reported above are what the researchers expected to find in the participants' blood. Overall, this means that the amount of AZD5718 that got into the participants' blood was high enough for it to possibly be able to work.

What medical problems happened 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 drugs. 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.

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?

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

How has this study helped patients and researchers?

This study helped researchers learn more about how AZD5718 acts in the body in healthy male 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 AZD5718 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 **"NCT03948451"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D7550C00007"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase I, Open-Label Study to Characterise the Absorption, Distribution, Metabolism and Excretion following a Single Oral Dose of [^{14}C] AZD5718 in Healthy Male Volunteers

AstraZeneca Protocol Number: D7550C00007

National Clinical Trials number: NCT03948451

AstraZeneca AB sponsored this study and has its headquarters at 151 85 Södertälje, Sweden.

The phone number for the AstraZeneca Information Center is +1-877-240-9479 and the email is information.center@astrazeneca.com.

Thank you!

Clinical study participants and their families 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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