AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD5718

Study Title: A study to learn how different forms of AZD5718 act in the blood in healthy male participants

Protocol Number: D7550C00008

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD5718.

AstraZeneca AB sponsored this study and thinks it is important to share the results. 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 study doctor or staff at your study site.

Who took part in the study?

The participants in this study were healthy men who were 25 to 55 years old when they joined.

The study included 12 participants in the United Kingdom.

Why was the research needed?

Researchers are looking for a better way to treat coronary artery disease, also called CAD. 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.

CAD is a condition that happens when the heart arteries become narrow or blocked. This can cause heart attack, stroke, and other medical problems.

CAD can happen when certain proteins in the body cause swelling in the heart arteries. The study drug, AZD5718, was developed to stop this swelling by blocking these proteins from sending signals to the body.

In this study, the researchers wanted to learn how different forms of AZD5718 acted in the participants' blood. They also wanted to find out if the participants had any medical problems during this study.

This information may help researchers decide which forms and doses of AZD5718 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 did the different forms of AZD5718 act in the blood?
- What medical problems happened during the study?

The answers to these questions are important to know before other studies can be done to find out if AZD5718 improves the health of people who have CAD.

What treatments did the participants take?

There were 5 forms of AZD5718 in this study. There were 2 forms that contained a lower dose of AZD5718, and 3 forms that contained a higher dose of AZD5718. All of the forms were taken as tablets by mouth.

The participants took all 5 forms. First, they took the 2 forms that contained the lower dose of AZD5718. Then, the researchers studied the results. Once they determined that the dose was safe, the researchers gave the participants the 3 forms that contained the higher dose of AZD5718.

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

The chart below shows the treatments the participants took.

	Form 1 of AZD5718 (12 participants)	**Form 2 of AZD5718 (12 participants)**	**Form 3 of AZD5718 (12 participants)**	**Form 4 of AZD5718 (12 participants)**	**Form 5 of AZD5718 (12 participants)**
	higher dose of AZD5718	higher dose of AZD5718	lower dose of AZD5718	lower dose of AZD5718	higher dose of AZD5718
	Tablet by mouth				
	Once				

What happened during the study?

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

The chart below shows what happened during the study.

Before the participants took treatment

1 visit

The study doctors checked to make sure the participants could join the study.

The study doctors:

- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- did a physical examination
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

About 4 weeks

While the participants took treatment

1 visit

- The participants stayed at their study site and took all 5 forms of AZD5718, but in a different order.
- There was a 6-day period in between taking each form of AZD5718.

The study doctors:

- took blood samples
- continued checking the participants' health and asking them how they were feeling

Up to about 6 weeks

After the participants took treatment

1 visit

The study doctors checked the health of the participants.

About 1 week after treatment ended

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 did the different forms of AZD5718 act in the blood?

To answer this question, the study doctors took blood samples from the participants throughout the study.

In these samples, the study doctors measured:

- The average total level of AZD5718 in the blood during treatment
- The average total level of AZD5718 in the blood at the end of treatment
- The average highest level of AZD5718 in the blood during treatment
- The total level of AZD5718 in the blood 24 hours after each treatment

Overall, the researchers found that the levels of AZD5718 in the blood were highest when the participants took Form 5. The researchers also found that overall, these levels were lowest when they took Form 4.

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 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 the study drug.

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?

There were 33.3% of participants who had adverse reactions during this study. This was 4 out of 12 participants.

None of the participants left this study due to adverse reactions.

What serious adverse reactions happened during this study?

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

None of the participants died due to serious adverse reactions during this study.

What adverse reactions happened during this study?

The most common adverse reaction during this study was pain in the stomach area.

The table below shows the adverse reactions that happened during this study. Some of the participants had more than 1 adverse reaction.

Adverse reactions during this study

Adverse reaction	**Form 1** (out of 12 participants)	**Form 2** (out of 12 participants)	**Form 3** (out of 12 participants)	**Form 4** (out of 12 participants)	**Form 5** (out of 12 participants)
Pain in the stomach area	0.0% (0)	8.3% (1)	8.3% (1)	8.3% (1)	0.0% (0)
Constipation	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Headache	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Feeling tired	0.0% (0)	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Feeling unsteady while moving	0.0% (0)	8.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Increased blood creatine phosphokinase (a possible sign of injury to the muscles, heart, or brain)	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)	0.0% (0)
Decreased sense of taste	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)	0.0% (0)
Dizziness	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)
Itchy skin	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	8.3% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about how different forms of AZD5718 acted in the blood 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 1 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 **"NCT04210388"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D7550C00008"** into the search box, and click **"Find a Study"**.

Full Study Title: A Randomized, Single-dose, Open-label, Single-center, Crossover Study to Assess the Relative Bioavailability and Safety of Different Formulations of AZD5718 in Healthy Volunteers

AstraZeneca Protocol Number: D7550C00008

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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