Clinical Study Results

Research Sponsor: AstraZeneca AB

Drugs Studied: AZD5718

Study Title: A study to learn how AZD5718 acts in the blood of healthy participants

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 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 researchers asked for the help of healthy men and women. The participants in this study were 22 to 54 years old when they joined.

The study included 14 male 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 researchers wanted to find out how much AZD5718 got into the blood of healthy participants at 3 different doses. Learning how different doses act in the blood helps researchers decide what dose to give 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 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?

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

In this study, all of the participants took AZD5718 as tablets by mouth. The doses of AZD5718 were:

- Dose 1 - low
- Dose 2 - medium
- Dose 3 - high

There were 6 different groups of participants in the study. Each group took each of the 3 doses in a different order.

A computer programme was used to randomly choose the order in which each group of participants took these doses. 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.

The participants stayed overnight at their study site for a total of 12 days. During this time, they took 3 single doses of AZD5718. The chart below shows when they took these doses:

Day	1	2	3	4	5	6	7	8	9	10	11	12
AZD5718		x				x				x		

What happened during the study?

The study started in September 2019 and ended in October 2019.

Up to 4 weeks before the participants took study treatment, they visited their study site 1 time. At this visit, the study doctors checked the health of the participants to make sure they could join the study.

The study doctors also:

- did a physical exam and asked about the participants' medications and any medical problems
- measured the participants' blood pressure and took their pulse rate
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG

While the participants stayed at the study site for 12 days, the study doctors repeated most of the tests and measurements that they had done before the participants took study treatment. The participants also took 3 single doses of AZD5718.

Up to 7 days after the participants took study treatment, they visited their study site 1 time. At this visit, the study doctors checked the participants' health and did an ECG.

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 change.

The websites listed at the end of this summary may have a full report of the study results.

How much AZD5718 got into the participants' blood?

To answer this question, the study doctors took blood samples from the participants before and after each dose of the study drug. 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

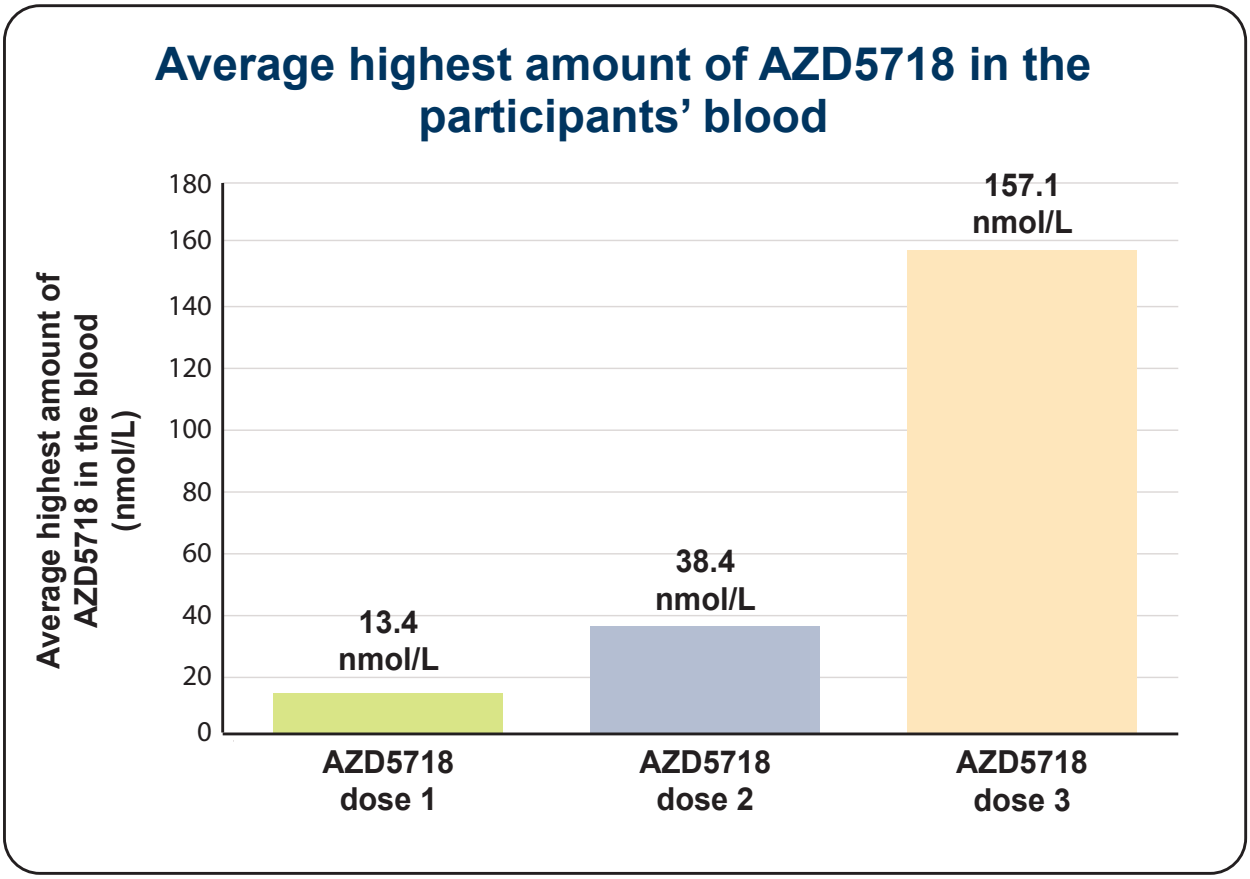
The researchers found that for both measurements, the average amounts of AZD5718 in the blood corresponded with the levels of doses the participants took. This means they were lowest when the participants took dose 1 and highest when they took dose 3.

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 each dose was:

- 13.4 nmol/L when the participants took dose 1 of AZD5718
- 38.4 nmol/L when the participants took dose 2 of AZD5718
- 157.1 nmol/L when the participants took dose 3 of AZD5718

The chart below shows these results:



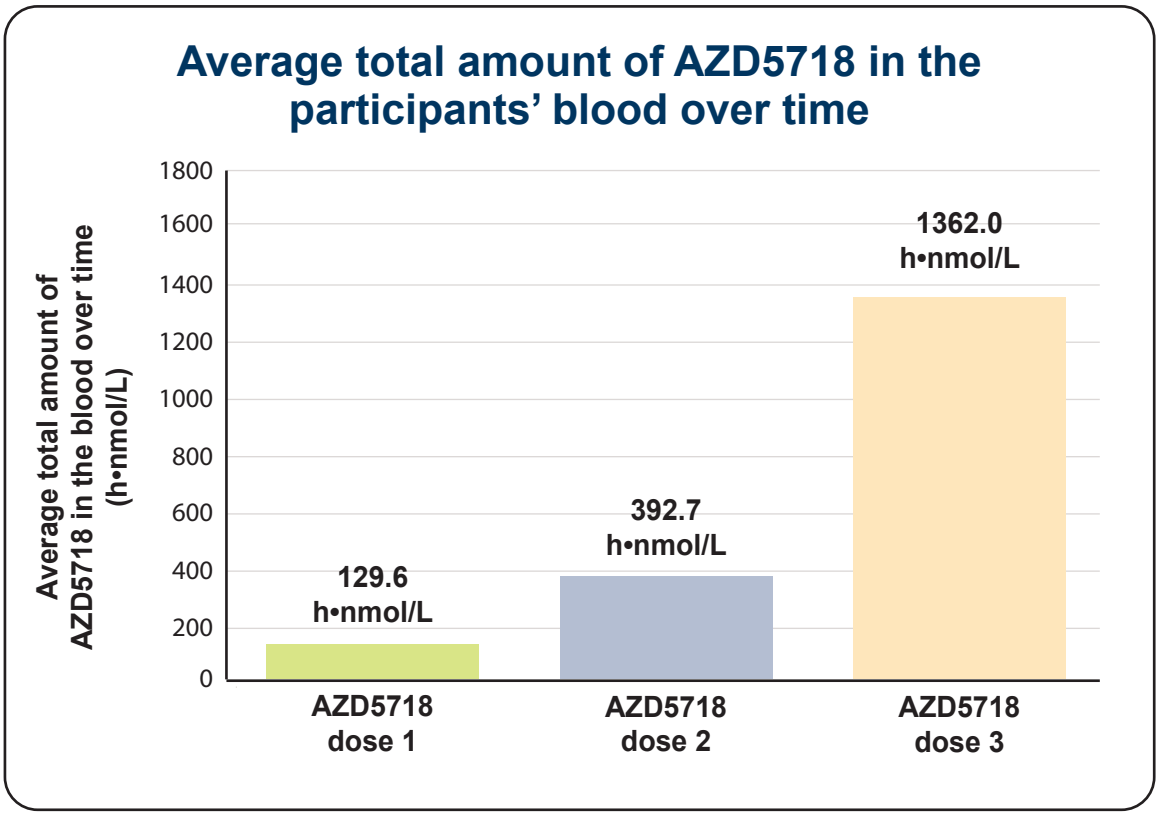
Average total amount of AZD5718 over time

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

- 129.6 h•nmol/L when the participants took dose 1 of AZD5718
- 392.7 h•nmol/L when the participants took dose 2 of AZD5718
- 1362.0 h•nmol/L when the participants took dose 3 of AZD5718

The results for dose 1 of AZD5718 here include only 12 out of the 14 participants. This was because for 2 participants, the amount of AZD5718 in the blood was too low to be measured.

The chart below shows these results:



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 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 21.4% of participants who had adverse reactions during this study. This was 3 out of 14 participants.

- 7.1% of participants had an adverse reaction while taking dose 1 of AZD5718. This was 1 out of 14 participants.
- 7.1% of participants had an adverse reaction while taking dose 2 of AZD5718. This was 1 out of 14 participants.
- 14.3% of participants had an adverse reaction while taking dose 3 of AZD5718. This was 2 out of 14 participants.

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

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

What adverse reactions happened during this study?

The most common adverse reactions were diarrhoea and headache.

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

Adverse reactions that happened in the study

Adverse reaction	AZD5718 dose 1 (out of 14 participants)	AZD5718 dose 2 (out of 14 participants)	AZD5718 dose 3 (out of 14 participants)
Diarrhoea	0.0% (0)	0.0% (0)	14.3% (2)
Headache	7.1% (1)	7.1% (1)	0.0% (0)
Stomach pain	0.0% (0)	0.0% (0)	7.1% (1)
Swollen belly	0.0% (0)	0.0% (0)	7.1% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about how much AZD5718 got into the blood of healthy men.

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 **"NCT04087187"** into the search box, and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2019-002796-33"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D7550C00009"** into the search box, and click **"Find a Study"**.

Full Study Title: A Randomized, 3-period, 3-treatment, Single-dose, Open-label, Single-center, Crossover Study to Assess the Pharmacokinetics of 3 Doses of AZD5718

AstraZeneca Protocol Number: D7550C00009

National Clinical Trials number: NCT04087187

AstraZeneca AB, sponsored this study and has its headquarters in Södertälje, Sweden.

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

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.

CISCRP
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