Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca AB

Drug Studied: AZD5718

Study Title: A study to learn how different formulations of AZD5718 act in the body

Thank you!

Thank you to the participants who took part in the clinical trial 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 this study and have questions about the results, please speak with the doctor or staff at your study site.

What is happening with the study now?

The study started in February 2018 and ended in April 2018. The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report. The study included 14 participants in England.

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 patients to take, researchers do clinical studies to find out how safe it is and how it works.

One major cause of CAD is chronic inflammation. Inflammation is an important process that helps fight disease and infection. But, for patients with CAD, chronic inflammation can make the disease worse.

Researchers think AZD5718 can help patients with CAD by reducing chronic inflammation.

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

- Which new formulation of AZD5718 acted the most like the AZD5718 tablets that were tested in previous studies?
- Did taking AZD5718 with food change the way AZD5718 behaved in the body?
- What medical problems did the participants have during the study?

These questions are important to answer before more studies can be done to find out if AZD5718 improves the health of people with CAD.

The researchers asked for the help of healthy men and women, but only men joined the study. Everyone in the study was 25 to 51 years old when they joined.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participant knew what the participant was taking.

Each participant took 5 different formulations of AZD5718 tablets. The tablets were made in different ways or had different amounts of AZD5718 in them.

- **Formulation 1:** These tablets each had 100 milligrams, also called mg, of AZD5718. The participants took 2 of these tablets, for a total dose of 200 mg. This formulation of the tablet had been tested in another study.
- **Formulations 2, 3, and 4:** These tablets each had 100 mg of AZD5718. The participants took 2 of each of these types of tablets, for a total dose of 200 mg for each tablet formulation. These formulations were all new and had not been tested in other studies.
- **Formulation 5:** These tablets each had 50 mg of AZD5718. The participants took 1 of these tablets, for a total dose of 50 mg. This formulation was also new and had not been tested in other studies.

A computer program was used to randomly choose the order that participants received each of the formulations. Researchers do this so that comparing the results of each formulation was as accurate as possible.

What happened during the study?

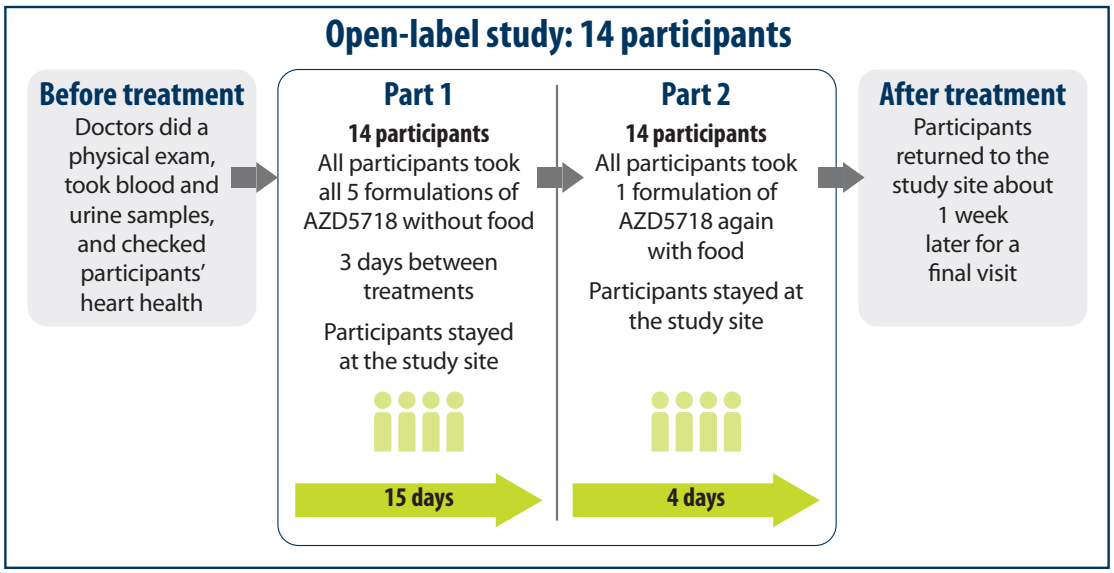
Before the participants started taking AZD5718, the doctors did a physical exam and asked participants about their medical history. They checked participants' heart health using an electrocardiogram, also called an ECG.

In Part 1 of the study, the participants stayed at the study site for at least 15 days. Each participant took the 5 different formulations of AZD5718. They waited at least 3 days after taking 1 formulation before they took the next formulation. The participants fasted for at least 10 hours before they took each formulation. This meant that the participants did not eat or drink anything except water for at least 10 hours before taking each treatment. Participants were allowed to have water up until 1 hour before taking each treatment. The researchers wanted to learn how much AZD5718 got into the blood for each formulation of AZD5718. They compared the new formulations that had not been tested in other studies with the formulation that had been tested before. Based on what they learned, they chose 1 of the new formulations of AZD5718 and used this formulation in Part 2.

In Part 2 of the study, the participants stayed at the study site for at least 4 days. Each participant took the formulation of AZD5718 that was chosen from Part 1. But this time they took it right after eating a meal. The researchers wanted to learn if there was a change in how much AZD5718 got into the blood when the formulation they chose from Part 1 was taken with food.

Throughout the study, the doctors took blood and urine samples. They also asked participants about any medications they were taking and any medical problems they were having.

The figure below shows how the study was done.



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.

Which new formulation of AZD5718 acted the most like the AZD5718 tablets that were tested in previous studies?

The researchers looked at:

- the amount of AZD5718 in the blood overall
- the maximum amount of AZD5718 in the blood at any time
- the amount of AZD5718 in the blood at 24 hours after taking AZD5718

They compared 4 different formulations of AZD5718 with a formulation that had already been tested in a previous study. Based on what they learned, the researchers chose 1 of the formulations taken as a 200 mg dose for Part 2 of the study.

Did taking AZD5718 with food change the way AZD5718 behaved in the body?

No. The researchers found that there was no meaningful difference in the amount of AZD5718 in the blood when the formulation in Part 2 was taken with food.

What medical problems did the participants have 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.

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.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

There were 14.3% of participants with adverse reactions during the study. This was 2 out of 14 participants. None of the participants stopped taking AZD5718 because of adverse reactions they had during the study.

What adverse reactions did the participants have?

Dizziness and headache were the only adverse reactions during the study:

- There were 14.3% of participants who felt dizzy. This was 2 out of 14 participants.
- There were 7.1% of participants who had a headache. This was 1 out of 14 participants.

All of these adverse reactions happened during the first part of the study.

How has this study helped participants and researchers?

This study helped researchers learn more about how different formulations of AZD5718 work in healthy 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 a full report of the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03420092"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2017 004303 43"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D7550C00005"** into the search box, and click **"Find a Study"**.

Full Study Title: A Randomized, 6-period, 6-treatment, Single-dose, Open-label, Single-center, Crossover Study to Assess the Relative Bioavailability of Different Formulations of AZD5718 and the Food Effect of the Selected Formulation of AZD5718 in Healthy Volunteers

AstraZeneca Protocol Number: D7550C00005

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.

Thank you!

Clinical trial 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 participants.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Center for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organization focused on educating and information 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
One Liberty Square, Suite 1100 • Boston, MA 02109
1-877-MED-HERO • www.ciscrp.org