Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD5718

Study Title: A study to learn about the safety of AZD5718 when taken by healthy Japanese men

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 for you.

If you participated in the 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 January 2018 and ended in June 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 32 participants in the United States.

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.

CAD can cause the major blood vessels to become thick and narrow. This decreases or cuts off the flow of blood and oxygen to the heart, which can cause a heart attack. Researchers think that the drug AZD5718 may be able to help decrease the chance of a heart attack by making these blood vessels less thick and narrow.

In this study, the researchers wanted to find out about the safety of AZD5718 in healthy participants.

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

- Did the participants' test results and measurements of safety change throughout the study?
- 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 help find out if AZD5718 improves the health of people with heart disease.

The researchers asked for the help of healthy Japanese men living in the United States. Everyone in the study was 21 to 49 years old when they joined.

What kind of study was this?

This was a "single-blind" study. This means the researchers knew what the participants were taking but the participants did not.

During this study, the participants took either AZD5718 or a placebo. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the drug are actually caused by the drug.

The participants took AZD5718 or the placebo by mouth as liquid. The doses were measured in milligrams, also called mg. There were 4 different groups of participants. Each group was given 1 of the following doses: 60 mg, 180 mg, 360 mg, or 600 mg.

For each group, a computer program was used to randomly choose if the participants took one of the doses of AZD5718 or the placebo. This helps make sure the treatments are chosen fairly. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

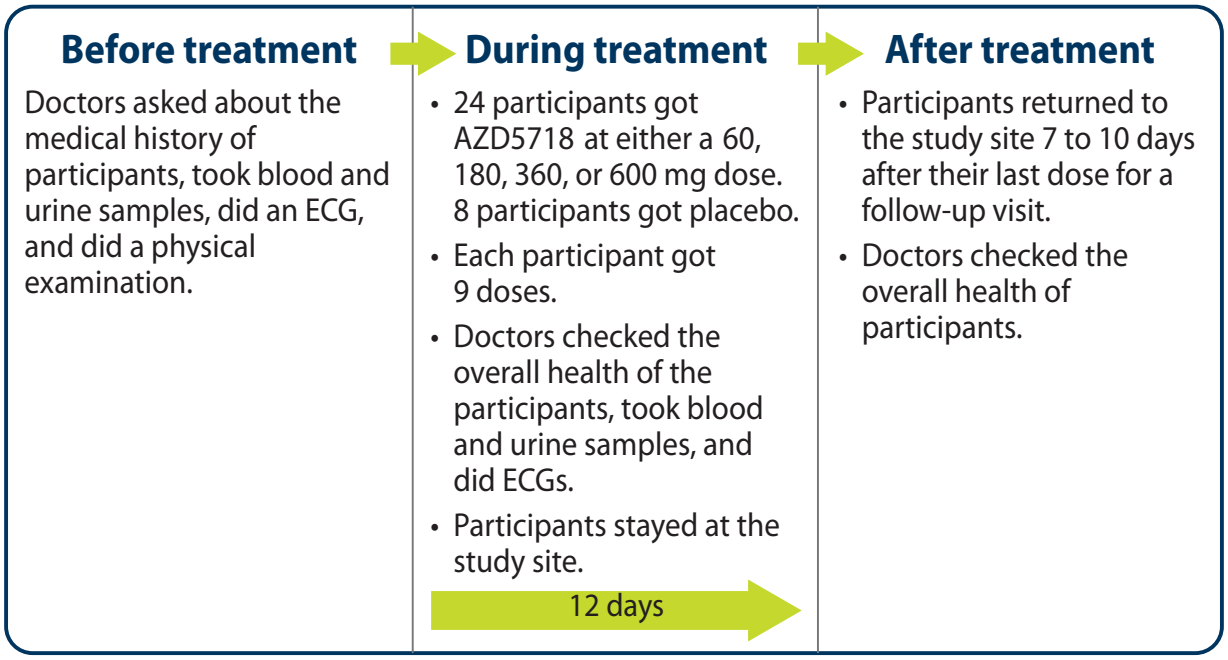
Before the participants started treatment, the doctors checked their overall health to make sure they could join the study. The doctors:

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

During treatment, the participants stayed at the study site for 12 days. During this time, they took AZD5718 or the placebo once daily on Day 1 and Days 3 to 10. This was a total of 9 doses. Each day, the doctors checked the overall health of the participants, took blood and urine samples, and did ECGs.

The researchers studied the participants' results after treatment in one group before the next group started treatment.

7 to 10 days after treatment, the participants returned to the study site. During this visit, the doctors checked their overall health.



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.

Did participants' test results and measurements of safety change during the study?

Some of the participants' test results changed during the study, but the changes were too small for the researchers to know if the study treatments caused the changes.

To answer this question, the doctors looked at the results of these tests:

- vital signs such as blood pressure, heart rate and breathing rate
- ECGs
- physical examinations
- blood and urine samples

The doctors did these tests before the participants took the study treatment and throughout the study.

What medical problems did the participants have during the study?

This section is a summary of medical problems called "adverse events" that participants had during the study. An adverse event is any sign or symptom of a medical problem that participants have. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study drug.

An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

How many participants had serious adverse events?

None of the participants had a serious adverse event during the study.

How many participants had adverse events?

There were 41.7% of the participants who had an adverse event while taking AZD5718 during the study. This was 10 out of 24 participants.

There were 62.5% of the participants who had an adverse event while taking the placebo during the study. This was 5 out of 8 participants.

What adverse events did participants have?

The most common adverse event was a red, itchy rash caused by direct contact with a substance or surface. This happened in:

- 29.2% of participants taking AZD5718. This was 7 out of 24 participants.
- 50% of participants taking a placebo. This was 4 out of 8 participants.

The rest of this section is a summary of the medical problems the participants had during the study that the doctors thought might be related to the study treatment. 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 treatment. A lot of research is needed to know whether a treatment 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 a serious adverse reaction during the study.

How many participants had adverse reactions?

There were 3.1% of the participants who had an adverse reaction during the study. This was 1 out of 32 participants. The adverse reaction was constipation, and it happened in a participant taking the placebo.

None of the participants who took AZD5718 had an adverse reaction.

How has this study helped participants and researchers?

The results from this study helped the researchers learn more about the safety of AZD5718 in healthy Japanese participants. The results will help researchers make decisions about using AZD5718 to treat patients with heart disease and the dose to use in future studies.

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 ongoing and 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 **"NCT03400488"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D7550C00004"** into the search box and click **"Find a Study"**.

Full Trial Title: A Phase I, Randomized, Single-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AZD5718 After Single and Multiple Ascending Dose Administration to Healthy Japanese Men

AstraZeneca Protocol Number: D7550C00004

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 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 participants.