

Clinical Study Results



Research sponsor: AstraZeneca AB

Drug studied: AZD5718

Short study title: A study to learn if AZD5718 is safe to take with rosuvastatin for people with heart disease

Thank you!

Thank you for taking part in the clinical study for the drug AZD5718. This drug is being developed to treat people with coronary artery disease, also known as CAD. You helped researchers learn how AZD5718 acts in the body when taken with rosuvastatin, which is an approved drug for treating CAD. You also helped the researchers learn if AZD5718 causes medical problems. The study started in November 2016 and ended in March 2017.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study with you and the public. An independent, non-profit organization called CISC RP prepared this summary of the study results. We hope it helps you understand and feel proud of your important role in medical research.

If you participated in the study and have questions about the results, please speak with the doctor or staff at your study site.

Why was the research needed?

Researchers are looking for a better way to treat CAD. Before a drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

In this study, the researchers wanted to find out if healthy participants had any medical problems during the study. They also wanted to find out how AZD5718 works in the body. This information is important to know before other studies can be done to find out if AZD5718 improves the health of people with CAD.

CAD is a disease that can cause damage to blood vessels in the heart. One major cause of CAD is the build-up of cholesterol in the arteries near the heart. This build-up can lead to heart failure and other serious medical problems.

Another 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.

The other drug in this study, rosuvastatin, is already approved to treat patients with CAD. Rosuvastatin treats CAD by reducing cholesterol build-up in the arteries. The study drug, AZD5718, may help patients with CAD by reducing chronic inflammation.

The researchers in this study wanted to learn how AZD5718 affects people with CAD who are also taking rosuvastatin. To answer the questions in this study, the researchers asked for the help of healthy volunteers.

The main question researchers wanted to answer in this study was:

- How did rosuvastatin act in the body when taken alone compared to when taken with AZD5718?

What kind of study was this?

This was an “open-label” study. This means the study doctors and the participants knew what the participants were taking.

A computer program was used to randomly choose the treatment each participant took. 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.

What happened during the study?

There were 5 drug doses in this study. Each participant took all 5 doses, but in a different order. The participants in this study visited their study site 7 times.

Before the study started, the doctors did a physical examination to make sure the participants could join the study. They also checked their heart health using an electrocardiogram, also known as an ECG. The doctors also asked about participants’ medical history, how they were feeling, and what medicines they were taking.

The study doses are listed below. The doses were taken either in pill form or in liquid form by mouth. Some doses were taken with food, and some doses were taken without food:

- Dose 1: rosuvastatin alone
- Dose 2: rosuvastatin combined with AZD5718
- Dose 3: AZD5718 only
- Dose 4: AZD5718 only
- Dose 5: AZD5718 only

There was a “washout period” of 7 days in between the 5 treatment periods. During the washout period, participants were not allowed to take certain medications. This means that their bodies had processed all of the medications in their blood, and the medications were “washed out” of their bodies.

What were the results of the study?

This is an overall summary of the main results from this study. The results each participant had might be different and may not be in this summary. A full list of the questions the researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it can also be found on these websites.

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.

How did rosuvastatin act in the body when taken alone compared to when taken with AZD5718?

The researchers wanted to learn how rosuvastatin acted in the bodies of participants when taken alone compared to when taken with AZD5718. Since only Dose 1 and Dose 2 had rosuvastatin in them, only the results for those doses are discussed below.

The researchers measured the average amount of rosuvastatin in the blood, the highest amount of rosuvastatin in the blood, and how long it took for rosuvastatin to reach its highest amount in the blood.

The researchers found that:

- The average amount of rosuvastatin in the blood of participants was similar when participants took Dose 1 or Dose 2.
- The participants had higher amounts of rosuvastatin in their blood when they took the drugs together in Dose 2 compared to when they took rosuvastatin alone in Dose 1.
- It took less time for rosuvastatin to reach its highest amount in the blood when participants took both drugs together in Dose 2 compared to than when they took rosuvastatin alone in Dose 1.

What medical problems did participants have?

The medical problems participants have during clinical studies that the doctors think might be related to the study drug are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study 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 adverse reactions that happened in this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. The websites listed at the end of this summary may have other information about medical problems that happened in this study.

How has this study helped patients and researchers?

The results presented here are for a single study. These results helped the researchers learn about how rosuvastatin acts in the body when it is taken with AZD5718 and if the combined drugs are safe to take for people with CAD.

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 these combined drugs 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 also can be found there.

- www.clinicaltrials.gov. Once you are on the website, type **NCT02963116** into the search box called “**Other Terms**”. Then, click “**Search**”.
- www.clinicaltrialsregister.eu. Once you are on the website, click “**Home and Search**”. Then, type **2016-003746-82** in the search box and click “**Search**”.

The full title of your study is: A Randomized, 5-Period, 5-Treatment, Single-Dose, Open-Label, Single-Center, Crossover Study to Estimate the Effect of AZD5718 on the Pharmacokinetics of Rosuvastatin, and to Assess the Relative Bioavailability of AZD5718 Oral Suspension vs AZD5718 IR Tablet Formulation and the Food Effect of AZD5718

The protocol number of your study is: D7550C00002

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.



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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