

**Research Sponsor:** AstraZeneca AB

**Drug Studied:** AZD5718

**Study Title:** This study was done to learn how AZD5718 worked in participants with coronary artery disease

**Protocol Number:** D7550C00003

## Thank you!

Thank you for taking part in the clinical study for the study drug AZD5718.

You and all of the participants helped researchers learn more about AZD5718 to help people with coronary artery disease, a type of heart disease.

AstraZeneca AB sponsored this study and believes it is important to share the results of the study with you and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you. 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 study doctor or staff at your study site.

# Overview of this study



## Why was the research needed?

Researchers are looking for a better way to treat coronary artery disease, a type of 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.



## What treatments did the participants take?

The participants in this study took 1 of 2 different doses of AZD5718 or a placebo. A placebo looks like a drug but does not have any medicine in it.



## What were the results of this study?

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

### > Did AZD5718 affect the levels of leukotriene E4 in the participants' urine?

Yes. Overall, AZD5718 reduced the levels of leukotriene E4 in the participants' urine. Leukotriene E4 is a molecule from the body's immune system that can cause inflammation and increase the risk of coronary artery disease.

### > What medical problems did the participants have during this study?

There were 9.4% of participants who had medical problems that the study doctors thought might be related to the study drug during the study. The most common medical problem was a headache.

More details about the results of this study are included later in this summary.



## Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on these websites.



## Who took part in this study?

The researchers asked for the help of men and women with coronary artery disease. The participants in this study were 37 to 76 years old when they joined. The participants all had sudden reductions in blood flow to the heart up to 4 weeks before joining the study. The participants did not have other serious heart or kidney problems.

The study included 129 participants in Denmark, Finland, and Sweden.



## Why was the research needed?

Researchers are looking for a different way to treat coronary artery disease. Before a drug can be approved for people 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 AZD5718 works in a small number of participants with coronary artery disease. They also wanted to find out if the participants had any medical problems during the study.

Coronary artery disease is the most common type of heart disease. It is also called coronary heart disease or ischemic heart disease. Coronary artery disease happens when fat and cholesterol build up in the blood vessels of the heart. These buildups are known as plaques, and they narrow the blood vessels. Together with inflammation, this can block blood flow. This can cause chest pain and discomfort. People with coronary heart disease are at high risk of having a heart attack.

Researchers have found that plaque buildup can be linked with high levels of an immune system molecule that causes inflammation called “leukotriene E4”. The study drug, AZD5718, was designed to reduce the amount of leukotriene E4 in the body. Researchers think that this will help reduce inflammation and plaque buildup.

In this study, the researchers wanted to find out if AZD5718 worked in participants with coronary artery disease.



## What was the purpose of this study?

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

- > Did AZD5718 affect the levels of leukotriene E4 in the participants' urine?
- > 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 coronary artery disease.



## What treatments did the participants take?

In this study, the participants took 1 of 2 different doses of 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.

This was a “single-blind” study. This means the researchers, study doctors, and other study staff knew what the participants were taking, but the participants did not.

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.




AZD5718 and the placebo were taken as tablets by mouth once a day. Overall:

- > 52 participants were planned to take a high dose of AZD5718
- > 25 participants were planned to take a low dose of AZD5718
- > 52 participants were planned to take the placebo

The researchers initially planned for the participants to take study treatment for 4 weeks. But, after some participants had already started the study, the researchers decided to change it to 12 weeks. Overall:

- > 38 participants were planned to take study treatment for 4 weeks
- > 91 participants were planned to take study treatment for 12 weeks

The chart below shows the treatments that the researchers planned to study.

	Treatment for 4 weeks			Treatment for 12 weeks		
	High dose of AZD5718	Low dose of AZD5718	Placebo	High dose of AZD5718	Low dose of AZD5718	Placebo
	18 participants	6 participants	14 participants	34 participants	19 participants	38 participants
	Tablets by mouth					
	Once a day for 4 weeks			Once a day for 12 weeks		

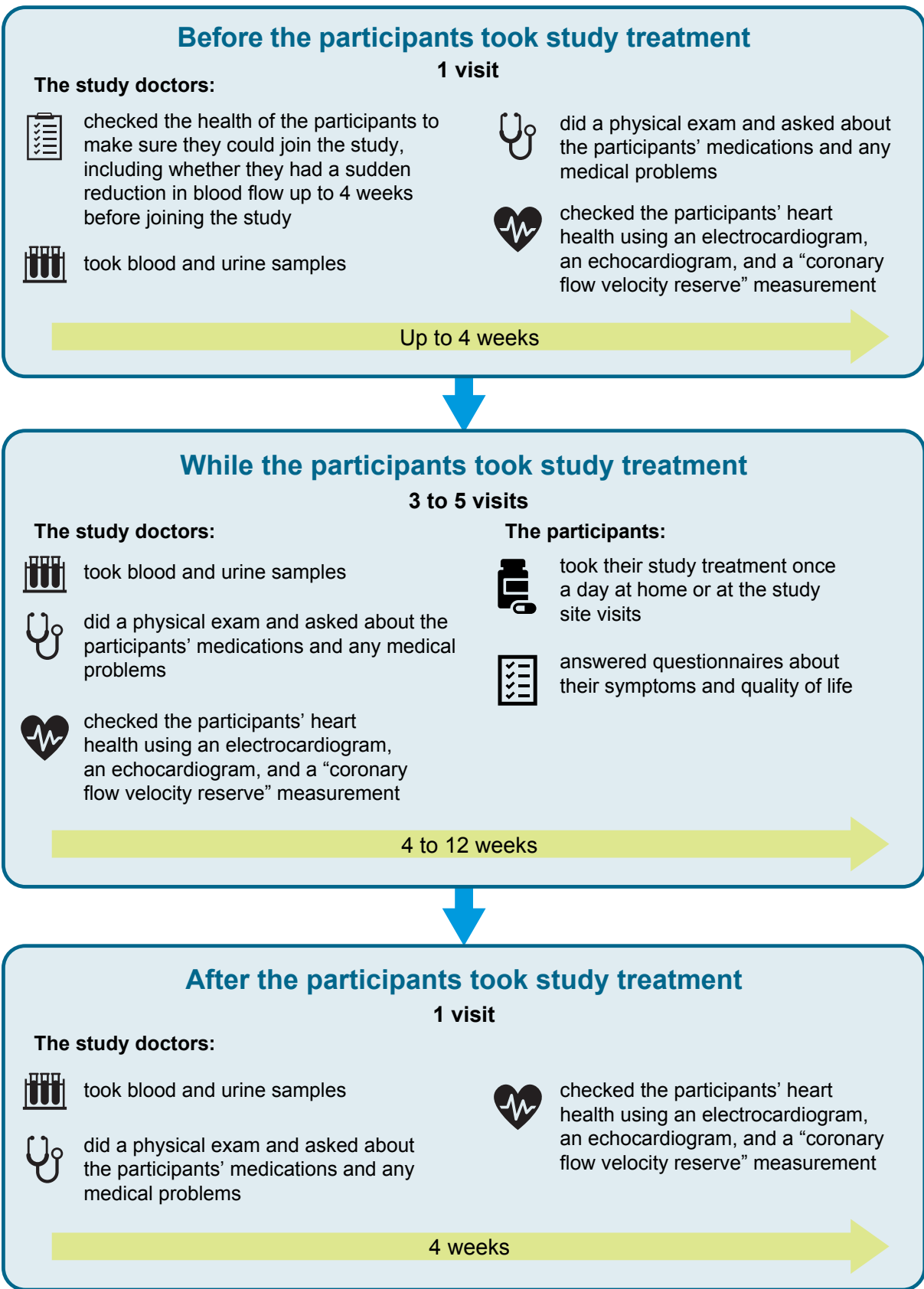


## What happened during this study?

The participants were in the study for up to about 4 months. But, the entire study took 2.5 years to finish.

The study started in October 2017 and ended in April 2020.

The chart below shows what happened during the study.





## What were the results of this 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. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When 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.

There was 1 participant who left the study before taking any study treatment. So, the results below are for 128 out of 129 participants.

### **Did AZD5718 affect the levels of leukotriene E4 in the participants' urine?**

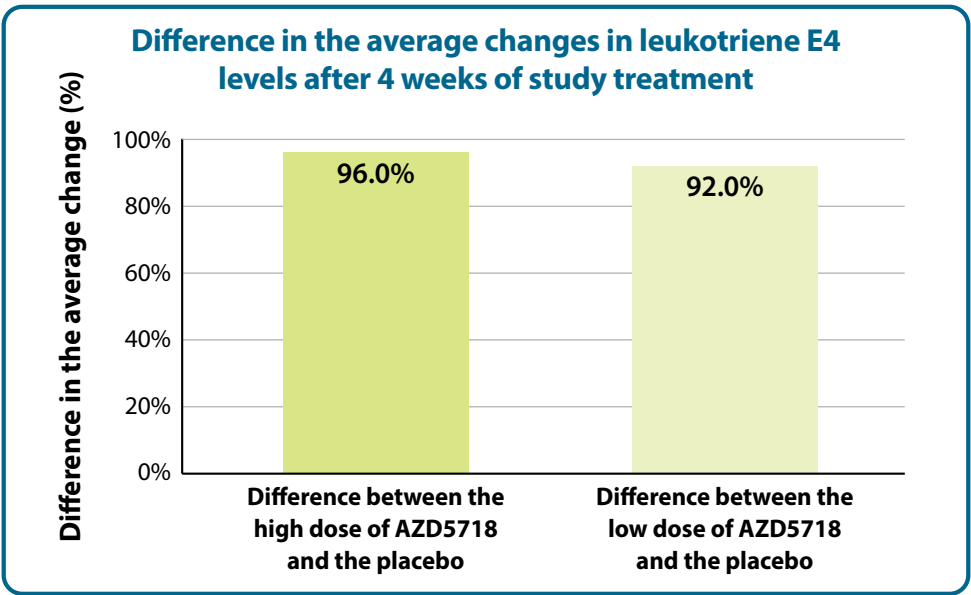
Yes. Overall, AZD5718 reduced the levels of leukotriene E4 in the participants' urine.

To answer this question, the researchers took urine samples from the participants during the study. The researchers measured leukotriene E4 levels before and after the participants took the study treatment. They measured any change in leukotriene E4 levels as a percentage. Then, they compared the differences in the average change between the participants who took the 2 different doses of AZD5718 and the participants who took the placebo.

**For the participants who took study treatment for 4 weeks,** the researchers found that the average change in leukotriene E4 levels in the participants' urine was:

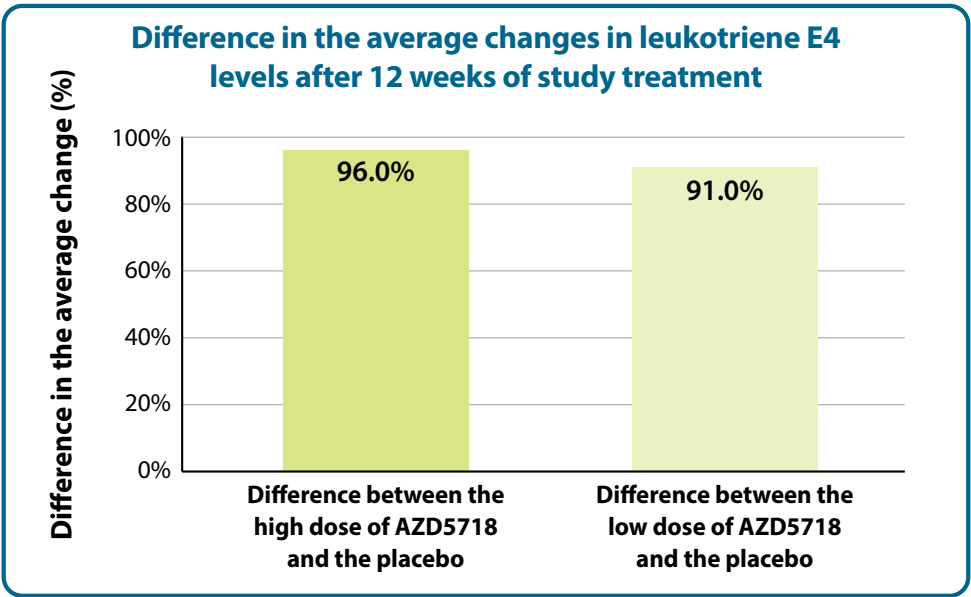
- > 96.0% different between the participants who took the high dose of AZD5718 and the participants who took the placebo
- > 92.0% different between the participants who took the low dose of AZD5718 and the participants who took the placebo

These results are shown in the chart below.



**For the participants who took study treatment for 12 weeks,** the researchers found that the average change in leukotriene E4 levels in the participants' urine was:

- > 96.0% different between the participants who took the high dose of AZD5718 and the participants who took the placebo
- > 91.0% different between the participants who took the low dose of AZD5718 and the participants who took the placebo







## 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 AZD5718.

The websites listed at the end of this summary may have more information about adverse reactions or other medical problems that happened during this study.

### Did any adverse reactions happen during this study?

	Treatment for 4 weeks			Treatment for 12 weeks		
	High dose of AZD5718 (out of 18 participants)	Low dose of AZD5718 (out of 6 participants)	Placebo (out of 13 participants)	High dose of AZD5718 (out of 34 participants)	Low dose of AZD5718 (out of 19 participants)	Placebo (out of 38 participants)
How many participants had adverse reactions?	11.1% (2)	16.7% (1)	0.0% (0)	8.8% (3)	5.3% (1)	13.2% (5)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped taking study treatment due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	2.9% (1)	5.3% (1)	0.0% (0)

## What serious adverse reactions happened during this study?

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

## What adverse reactions happened during this study?

The most common adverse reaction was a headache. The table below shows the adverse reactions that happened in the study.

	Treatment for 4 weeks			Treatment for 12 weeks		
	High dose of AZD5718 (out of 18 participants)	Low dose of AZD5718 (out of 6 participants)	Placebo (out of 13 participants)	High dose of AZD5718 (out of 34 participants)	Low dose of AZD5718 (out of 19 participants)	Placebo (out of 38 participants)
Breathlessness	5.6% (1)	0.0% (0)	0.0% (0)	2.9% (1)	0.0% (0)	0.0% (0)
Delayed sleep	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Eczema on the scalp	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Feeling hot	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Insomnia	5.6% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Decreased weight	0.0% (0)	16.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Anxiety	0.0% (0)	0.0% (0)	0.0% (0)	2.9% (1)	0.0% (0)	0.0% (0)
Diarrhea	0.0% (0)	0.0% (0)	0.0% (0)	2.9% (1)	0.0% (0)	0.0% (0)
Headache	0.0% (0)	0.0% (0)	0.0% (0)	2.9% (1)	5.3% (1)	5.3% (2)
Itchiness	0.0% (0)	0.0% (0)	0.0% (0)	2.9% (1)	0.0% (0)	0.0% (0)
Decreased levels of a thyroid hormone called TSH	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	5.3% (2)
Increased levels of a liver protein called ALT	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	2.6% (1)
Increased levels of a liver protein called AST	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	2.6% (1)
Increased levels of a blood protein called ALP	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	2.6% (1)
Vomiting	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)	2.6% (1)



## How has this study helped patients and researchers?

This study helped researchers learn more about AZD5718 for participants with coronary artery disease.

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](http://www.clinicaltrials.gov). Once you are on the website, type **"NCT03317002"** into the search box and click **"Search"**.
- > <http://www.clinicaltrialsregister.eu>. Once you are on the website, click "Home and Search", then type **"2017-001582-25"** in the search box, and click **"Search"**.
- > [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type **"D7550C00003"** into the search box, and click **"Find a Study"**.

**Full Study Title:** A 12-week, Randomized, Single-Blind, Placebo-controlled, Multi-centre, Parallel Group, Phase IIa Study to evaluate Efficacy, Safety and Tolerability of Oral AZD5718 After 4- and 12-Weeks of Treatment in Patients with Coronary Artery Disease (CAD)

**AstraZeneca AB Protocol Number:** D7550C00003

**National Clinical Trials number:** NCT03317002

**EudraCT Number:** 2017-001582-25

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

**The phone number** for the AstraZeneca Information Center is +1-877-240-9479.

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## Thank you!

Participants in clinical studies 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.

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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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