# Clinical Trial RESULTS

AstraZeneca

**Research Sponsor:** AstraZeneca AB

**Drugs Studied:** AZD5718

**National Clinical Trial #:** NCT02632526

**Protocol #:** D7550C00001

**Study Date:** February 2016 to August 2016

**Short Study Title:** A study in healthy male participants to investigate a new drug for the treatment of heart disease

## *Thank you!*

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for the drug AZD5718. This drug is being developed to treat heart disease. You and all of the other participants helped researchers learn how AZD5718 acts in the body and if it causes medical problems.

AstraZeneca AB, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope this summary helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

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# What's happened since my study ended?

Your study started in February 2016 and ended in August 2016. It included 96 participants at 1 study site in the United Kingdom. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

# Why was the research needed?

Before patients can take a new drug, the company developing it must do research studies to show that it is safe and effective. The first step in studying a new drug is to test it in healthy people. This means people without any serious health problems.

Your study drug, AZD5718, is being developed to treat heart disease.

Leukotriene B4, which is also called LTB4, is a substance your body makes naturally, and it leaves the body through urination. LTB4 can cause inflammation, which can result in redness, warmth, swelling, or pain in the body. Inflammation can cause heart disease or make heart disease worse if you already have it. So far, research has shown that AZD5718 lowers the amount of LTB4 your body makes. This could also lower inflammation and help those with heart disease.

In this study, researchers compared 2 forms of AZD5718, Liquid 1 and Liquid 2.

Both liquids had AZD5718 in them, but the AZD5718 in Liquid 1 had a different chemical makeup than the AZD5718 in Liquid 2. Researchers compared the 2 liquids to each other and to a liquid taken with placebo. Placebo looks like the study drug but contains no real medicine. Researchers wanted to know:

- What was the highest dose of AZD5718 that was safe to take?
- What medical problems did participants have after they got AZD5718?
- How did AZD5718 affect the body?

# What kind of study was this?

Your study was "single-blind". This means that the study staff knew which drug the participants took, but the participants did not. Study staff found out which drug each participant took after the participants' last visit. You and other participants got either AZD5718 or placebo.

All of the study participants were healthy men who were between 19 to 50 years old.

# What happened during the study?

This study had 2 parts, Part A and Part B. You were in either Part A or Part B. If you were in Part A, you were in the study for up to 6 weeks. If you were in Part B, you were in the study for up to 8 weeks.

Participants in Part A stayed at the study site for 3 days and returned for follow-up visits 1 day after leaving the study site and 7 to 10 days after leaving the study site. Participants in Part B stayed at the study site for 12 days and returned for a follow-up visit 7 to 10 days after leaving the study site.

Part A had 2 groups, and Part B had only 1 group. Part A participants got only 1 dose of the study drug or placebo. Part B participants got 1 dose of the study drug or the placebo every day for 10 days.

The treatments for both parts are listed below.

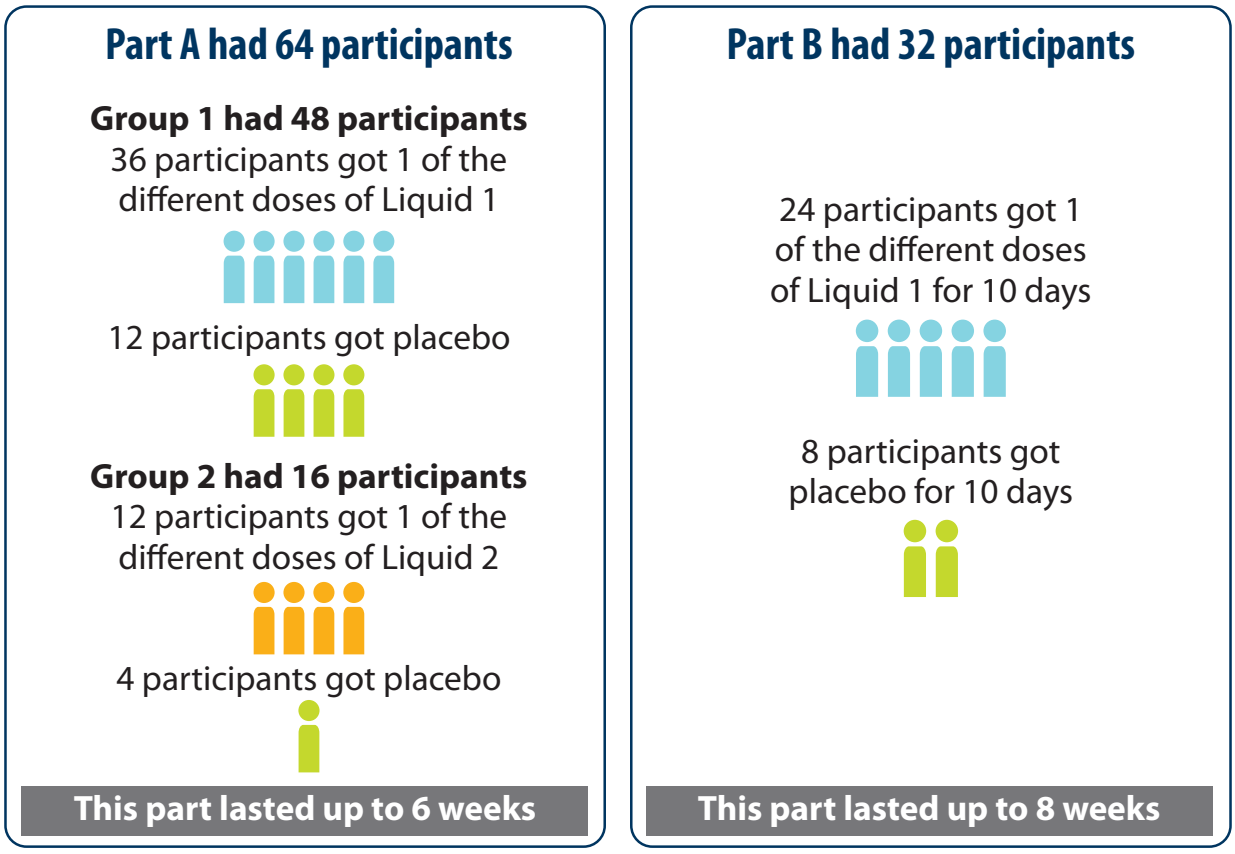
**Part A**

- Group 1— 36 participants got different doses of Liquid 1. The doses were 25, 50, 100, 300, 600, or 1200 milligrams, or mg. Twelve participants got placebo.
- Group 2— 12 participants got different doses of Liquid 2. The doses were 100 or 300 mg. Four participants got placebo.

**Part B**

- 24 participants got different doses of Liquid 1. The doses were 60, 180, 360, or 600 mg. Eight participants got placebo.

The figure below shows how the study was done.




During the study, researchers did blood and urine tests and physical examinations. They also checked your heart using an electrocardiogram, or ECG.

# What were the study results?

This section tells you results of some of the questions researchers asked in your study. They look at the results of many studies, like yours, to decide which medicines work best and are safest for patients. Further clinical studies with AZD5718 are currently planned.

### *What was the highest dose of AZD5718 that was safe to take?*

In this study, researchers gave participants several different doses of AZD5718. They wanted to learn if any of these doses could cause serious medical problems. A medical problem is considered serious when it is life-threatening, causes lasting problems, or requires hospital care. No one in your study had a serious medical problem. Because of this, researchers did not find the highest dose of AZD5718 that was safe to take. All of the doses of the study drug were safe to take.

## *What medical problems did participants have after they got AZD5718?*

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, researchers keep track of all medical problems that participants have during the study. These medical problems are called "adverse events" They may or may not be caused by the study drug.

### Part A

Out of the 36 participants who got Liquid 1 of the study drug, 15 (41.7%) had at least 1 medical problem. Out of the 12 participants who got Liquid 2 of the study drug, 2 (16.7%) had at least 1 medical problem. Out of the 12 participants who got placebo in Group 1, one (8.3%) had at least 1 medical problem. Out of the 4 participants who got placebo in Group 2, one (25.0%) had at least 1 medical problem.

### Part B

Out of the 24 participants who got Liquid 1 of the study drug, 10 (41.7%) had at least 1 medical problem. Out of the 8 participants who got placebo, 4 (50.0%) had at least 1 medical problem.

## *How many participants had medical problems in the study?*

The tables below and on the next page show how many participants in each group developed medical problems in the study. No participants stopped taking the study drug because of a medical problem.

| Part A Group 1 (Liquid 1) | Placebo (Out of 12 participants) | 25 mg AZD5718 (Out of 6 participants) | 50 mg AZD5718 (Out of 6 participants) | 100 mg AZD5718 (Out of 6 participants) | 300 mg AZD5718 (Out of 6 participants) | 600 mg AZD5718 (Out of 6 participants) | 1200 mg AZD5718 (Out of 6 participants) |
|---|---|---|---|---|---|---|---|
| How many participants developed medical problems? | 1 participant (8.3%) | 3 participants (50.0%) | 3 participants (50.0%) | 1 participant (16.7%) | 3 participants (50.0%) | 1 participant (16.7%) | 4 participants (66.7%) |

| Part A Group 2 (Liquid 2) | Placebo (Out of 4 participants) | 100 mg AZD5718 (Out of 6 participants) | 300 mg AZD5718 (Out of 6 participants) |
|---|---|---|---|
| How many participants developed medical problems? | 1 participant (25.0%) | 0 participants (0%) | 2 participants (33.3%) |

| Part B (Liquid 1) | Placebo (Out of 8 participants) | 60 mg AZD5718 (Out of 6 participants) | 180 mg AZD5718 (Out of 6 participants) | 360 mg AZD5718 (Out of 6 participants) | 600 mg AZD5718 (Out of 6 participants) |
|---|---|---|---|---|---|
| **How many participants developed medical problems?** | 4 participants (50.0%) | 2 participants (33.3%) | 3 participants (50.0%) | 2 participants (33.3%) | 3 participants (50.0%) |

### *How many participants developed serious medical problems?*

A medical problem is considered serious when it is life-threatening, causes lasting problems, or requires hospital care. No participants died in your study, and no participants developed serious medical problems. No safety concerns were raised during this study.

### *What were the most common medical problems?*

The table below shows the medical problems that happened in at least 2 participants in Part A, Group 1. All other medical problems happened in 1 participant.

| Part A Group 1 (Liquid 1) | Placebo (Out of 12 participants) | 25 mg AZD5718 (Out of 6 participants) | 50 mg AZD5718 (Out of 6 participants) | 100 mg AZD5718 (Out of 6 participants) | 300 mg AZD5718 (Out of 6 participants) | 600 mg AZD5718 (Out of 6 participants) | 1200 mg AZD5718 (Out of 6 participants) |
|---|---|---|---|---|---|---|---|
| **Headache** | 0 participants (0%) | 0 participants (0%) | 0 participants (0%) | 1 participant (16.7%) | 0 participants (0%) | 0 participants (0%) | 2 participants (33.3%) |

In Part A, Group 2, no medical problem happened in more than 1 participant.

The table below shows the medical problems that happened in at least 2 participants in Part B. All other medical problems happened in 1 participant.

| Part B (Liquid 1) | Placebo (Out of 8 participants) | 60 mg AZD5718 (Out of 6 participants) | 180 mg AZD5718 (Out of 6 participants) | 360 mg AZD5718 (Out of 6 participants) | 600 mg AZD5718 (Out of 6 participants) |
|---|---|---|---|---|---|
| **Headache** | 1 participant (12.5%) | 1 participant (16.7%) | 2 participants (33.3%) | 0 participants (0%) | 2 participants (33.3%) |
| **Heart beating harder or faster than normal, "fluttering," or skipping beats** | 0 participants (0%) | 1 participant (16.7%) | 2 participants (33.3%) | 0 participants (0%) | 0 participants (0%) |

## *How did AZD5718 affect the body?*

Researchers also wanted to know how AZD5718 affects the body. Researchers wanted to see if the drug lowered LTB4 in the body. So they tested blood samples from you and other participants to find out. They found that:

- Participants who got higher doses of AZD5718 (Liquid 1) had less LTB4 in their blood. LTB4 also left the blood faster.
- LTB4 left the blood faster in participants who got 100 or 300 mg of Liquid 1, compared to 100 or 300 mg of Liquid 2.

# Where can I learn more about the study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02632526.

Official study title: A Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AZD5718 After Single and Multiple Ascending Dose Administration to Healthy Male Subjects

Astra Zeneca AB, the sponsor of this study, has its headquarters in Södertälje, Sweden.

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

**The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.**

## *Thank you*

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.

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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 trials, nor is it involved in conducting clinical trials.

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