Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD4635

Study Title: A study to learn how different forms of AZD4635 act in the blood in healthy male participants

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD4635.

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 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 November 2018 and ended in April 2019. The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

This study included 21 participants in the United Kingdom.

Why was the research needed?

Researchers are looking for a better way to treat cancer. 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.

The study drug, AZD4635, is being developed to treat some cancers. In this study, the researchers compared a capsule form of AZD4635 with a liquid form of AZD4635, both taken by mouth. They wanted to learn how the different forms of AZD4635 acted in the blood of healthy participants.

The participants also took a drug called lansoprazole. Lansoprazole is a medicine that is normally used to help with acid reflux or heartburn. It changes the acidity of the stomach and may affect how much AZD4635 gets into the blood.

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

- Was the amount of AZD4635 in the participants' blood similar when given in each form?
- 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 that help find out if AZD4635 improves the health of people with cancer.

The researchers asked for the help of healthy men. Everyone in the study was aged 19 to 53 when they joined and did not smoke or use other nicotine products.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participants knew what the participants were getting. In this study, all of the participants got AZD4635. Each dose was 50 milligrams, also known as mg.

This study happened in 2 parts, and each part had different treatment periods. It was planned that all participants would complete both parts.

The chart below shows the treatments in each period.

Part 1	
Treatment Period A	1 dose of AZD4635 as a liquid after fasting
Treatment Period B	1 dose of AZD4635 as a capsule after fasting
Part 2	
Treatment Period C	1 dose of AZD4635 as a capsule after breakfast
Treatment Period D	1 dose of AZD4635 as a capsule after fasting 2 daily doses of a drug called lansoprazole for 4 days before taking AZD4635, and 1 dose 2 hours before taking AZD4635
Treatment Period E	1 dose of a different form of AZD4635 as a capsule after fasting 1 “tracer” injection into a vein, also called an intravenous or IV infusion, to allow the researchers to see how the treatment moves through the body
Treatment Period F	1 dose of a different form of AZD4635 as a capsule after fasting

In Part 1, a computer program was used to randomly choose the order in which each participant got each treatment. 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.

In Part 2, the participants completed Treatment Period C first, and then Treatment Period D. A computer program was also used to randomly choose the order in which each participant completed Treatment Periods E and F.

The participants waited up to 4 weeks between each treatment period.

What happened during the study?

Up to 28 days before the participants got study treatment, they visited their study site once. At this visit, the study doctors checked the overall health of the participants to make sure that they could join the study. The study doctors:

- asked the participants about their health and about any medications they were taking
- did a physical exam
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- did a breath test to check for smoking and alcohol use

The doctors also did these tests and measurements throughout the study.

Each treatment period lasted about 7 days. During each treatment period, the participants visited their study site on Day 1 and stayed overnight for 4 nights. During this time, the participants got their dose of AZD4635 in the morning on Day 2. The participants returned for 2 more visits on Days 6 and 7.

This is shown in the table below.

Day	1	2	3	4	5	6	7
Visit	Overnight					●	●
AZD4635		●					

During Treatment Period D, the participants also took 2 daily doses of lansoprazole at home for 4 days before they took AZD4635 and 1 dose 2 hours before they took AZD4635.

Within 7-10 days of getting their study treatment, the study doctors called the participants to ask about their health, medications, and any medical problems they were having.

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.

Was the amount of AZD4635 in the participants' blood similar when given in each form?

Yes. The amount of AZD4635 that got into the participants' blood was similar when they took AZD4635 as a capsule and when they took it as a liquid.

To answer this question, the study doctors took blood samples at different times after the participants got AZD4635 in Part 1. The study doctors measured the amount of AZD4635 in the participants' blood. They compared the liquid form results from Treatment Period A and the capsule form results from Treatment Period B. They measured:

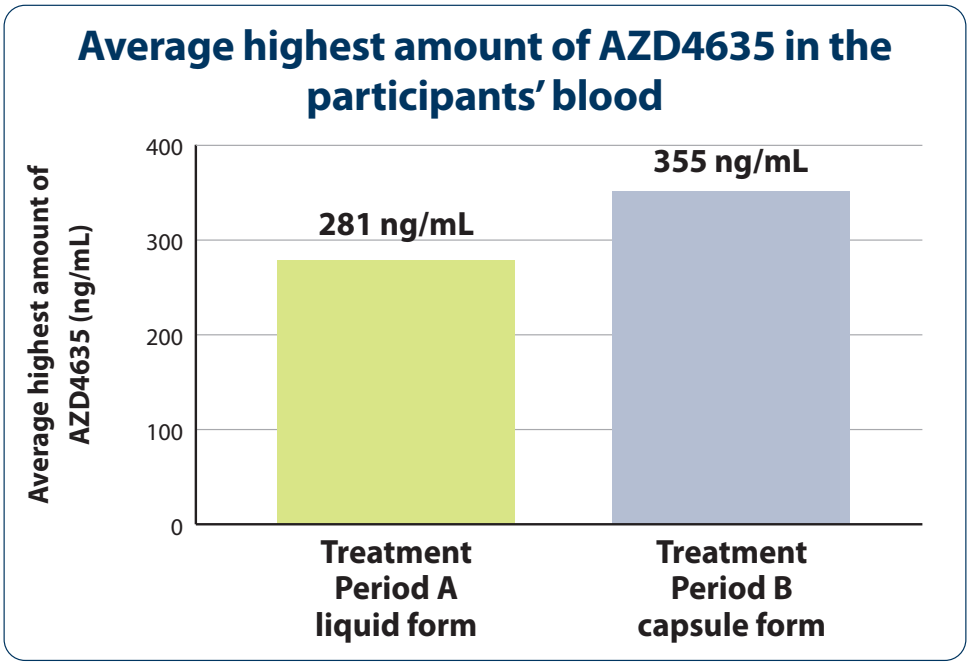
- the average highest amount of AZD4635 in the participants' blood
- the average total amount of AZD4635 in the participants' blood

Average highest amount of AZD4635 in the participants' blood

The average highest amount of AZD4635 was measured in nanograms per milliliter, also known as ng/mL. The researchers found that the average highest amount of AZD4635 in the participants' blood was:

- 281 ng/mL in Treatment Period A
- 355 ng/mL in Treatment Period B

This is shown in the chart below.

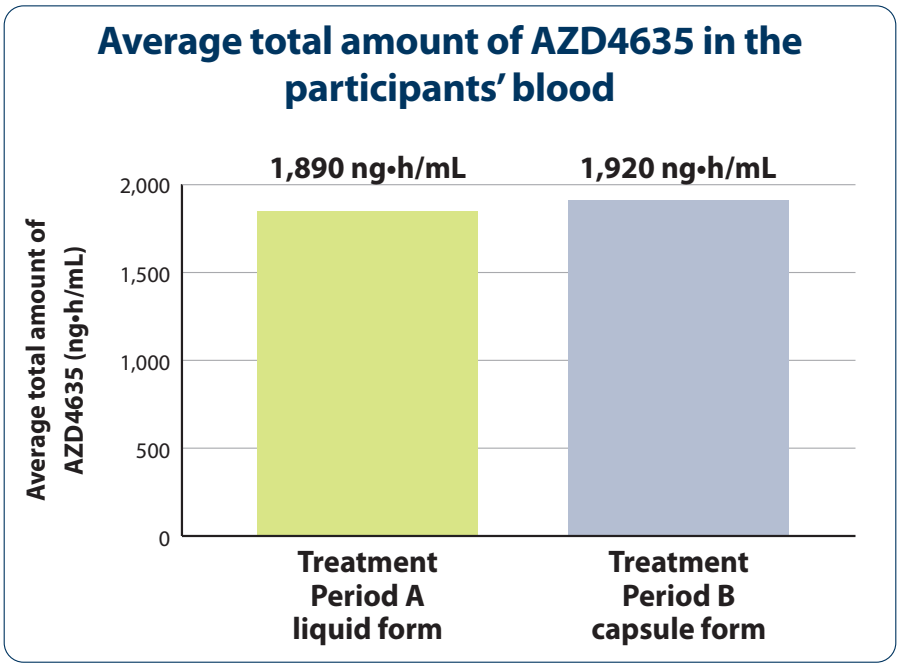


Average total amount of AZD4635 in the participants' blood

The average total amount of AZD4635 was measured in nanograms per milliliter per hour, also known as ng.h/mL. The researchers found that the average total amount of AZD4635 in the participants' blood was:

- 1,890 ng.h/mL in Treatment Period A
- 1,920 ng.h/mL in Treatment Period B

This is shown in the chart below.



What medical problems did 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 drugs. 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 drugs. 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.

Some participants did not complete all of the treatment periods. So, the results below include information for 20 participants in each treatment period.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

- 20% of participants had adverse reactions during **Treatment Period A** of the study. This was 4 out of 20 participants.
- 15% of participants had adverse reactions during **Treatment Period B** of the study. This was 3 out of 20 participants.
- 10% of participants had adverse reactions during **Treatment Period C** of the study. This was 2 out of 20 participants.
- 20% of participants had adverse reactions during **Treatment Period D** of the study. This was 4 out of 20 participants.
- 10% of participants had adverse reactions during **Treatment Period E** of the study. This was 2 out of 20 participants.
- 10% of participants had adverse reactions during **Treatment Period F** of the study. This was 2 out of 20 participants.

None of the participants left the study because of adverse reactions they had.

What adverse reactions did the participants have?

The most common adverse reaction was dizziness.

The table below shows the adverse reactions that happened during the study.

Adverse reactions during the study

Adverse reactions	Treatment Period A (out of 20 participants)	Treatment Period B (out of 20 participants)	Treatment Period C (out of 20 participants)	Treatment Period D (out of 20 participants)	Treatment Period E (out of 20 participants)	Treatment Period F (out of 20 participants)
Dizziness	15% (3)	10% (2)	10% (2)	15% (3)	10% (2)	10% (2)
Nausea	5% (1)	5% (1)	5% (1)	15% (3)	10% (2)	5% (1)
Extreme happiness	0% (0)	0% (0)	0% (0)	0% (0)	5% (1)	5% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about different forms of AZD4635 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 one study. Other studies may provide new information or different results.

Further clinical studies with AZD4635 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 **"NCT03710434"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D8730C00002"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase I, Open-Label Study to Assess the Pharmacokinetics and Relative Bioavailability of AZD4635 in Non-Smoking Healthy Male Subjects, with the Option to Assess Food Effect, pH Effect and Absolute Bioavailability

National Clinical Trials number: NCT03710434

AstraZeneca Protocol Number: D8730C00002

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.

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 patients.