Clinical Trial Results

AstraZeneca

Research Sponsor:	AstraZeneca
Drug Studied:	AZD4831
National Clinical Trial #:	NCT02712372
EudraCT #:	2015-005802-13
Protocol #:	D6580C00001
Study Date:	June 2016 to October 2016
Short Study Title:	A study in healthy male participants to see if AZD4831 is safe to take and how AZD4831 acts in the body

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 AZD4831. This drug is being developed to treat heart disease. You and all of the participants helped researchers learn if AZD4831 causes medical problems and how it acts in the body.

AstraZeneca, 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 it 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.

What's happened since my study ended?

Your study started in June 2016 and ended in October 2016. The study included 40 participants at 1 study site in Germany. 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 the drug 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.

The study drug, AZD4831, is being developed to treat heart disease. Heart disease includes many problems that can affect the heart, like blocked or clogged arteries, heart rhythm problems, and heart problems that you are born with. These problems could cause chest pain, stroke, or heart attacks.

In Part A of this study, researchers compared different doses of AZD4831 to a placebo. A placebo looks like the study drug but contains no real medicine. Researchers use a placebo so that they can compare the results of participants who take study drugs with the results of participants who take no medicine at all.

In Part B of this study, researchers studied the effects of food on taking 1 dose of AZD4831 alone.

Researchers wanted to know:

- How did AZD4831 act in the body?
- What medical problems did participants have after they took AZD4831?

What kind of study was this?

Part A of 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 the other participants took AZD4831 or a placebo. Which treatment participants took was decided by chance, like rolling dice. For every 6 participants who took AZD4831, 2 participants took a placebo.

Part B of your study was "open-label". This means that the participants and study staff knew what study drug each participant took. All of the participants in Part B of your study took AZD4831.

Your study included healthy men who were 19 to 50 years old.

What happened during the study?

This study had 2 parts: Part A and Part B. Participants began the study in Part A and could choose to join Part B after completing Part A. Participants who were in Part A were in the study for up to 5 weeks. Participants who were in both Part A and Part B were in the study for up to 6 weeks.

Another part of this study was planned, but it was not done. Instead, another study is being planned in its place.

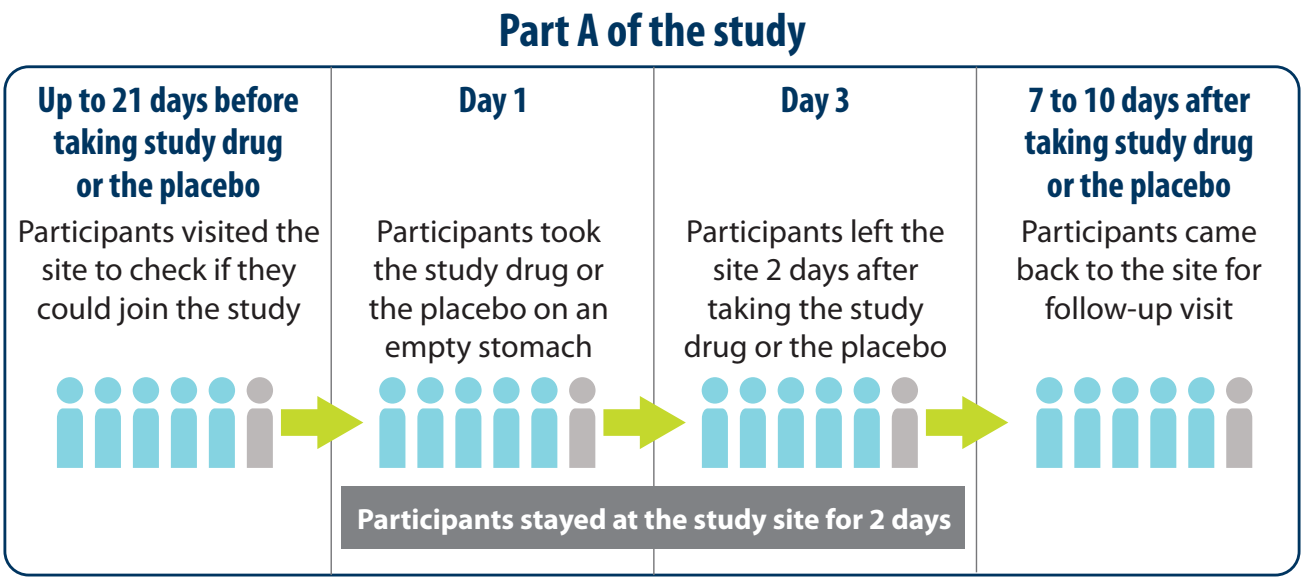
During Part A, all participants visited the study site up to 21 days before taking the study drug. At this visit, study doctors made sure that participants could join the study. On Day 1 of the study, participants took 1 dose of the study drug or the placebo on an empty stomach. Participants stayed at the study site for 2 days after taking the study drug on Day 1. Doctors at the study site took blood and urine samples every few hours after participants took the study drug. Participants left the study site on Day 3. About 7 to 10 days after taking the study drug, participants came back to the study site for a follow-up visit.

Which treatment participants took was determined by chance, like rolling dice. Participants had a 2 in 3 chance of taking AZD4831 and a 1 in 3 chance of taking the placebo. Overall, 30 participants took AZD4831, and 10 participants took the placebo during Part A.

Participants who took AZD4831 each took 1 of 5 doses:

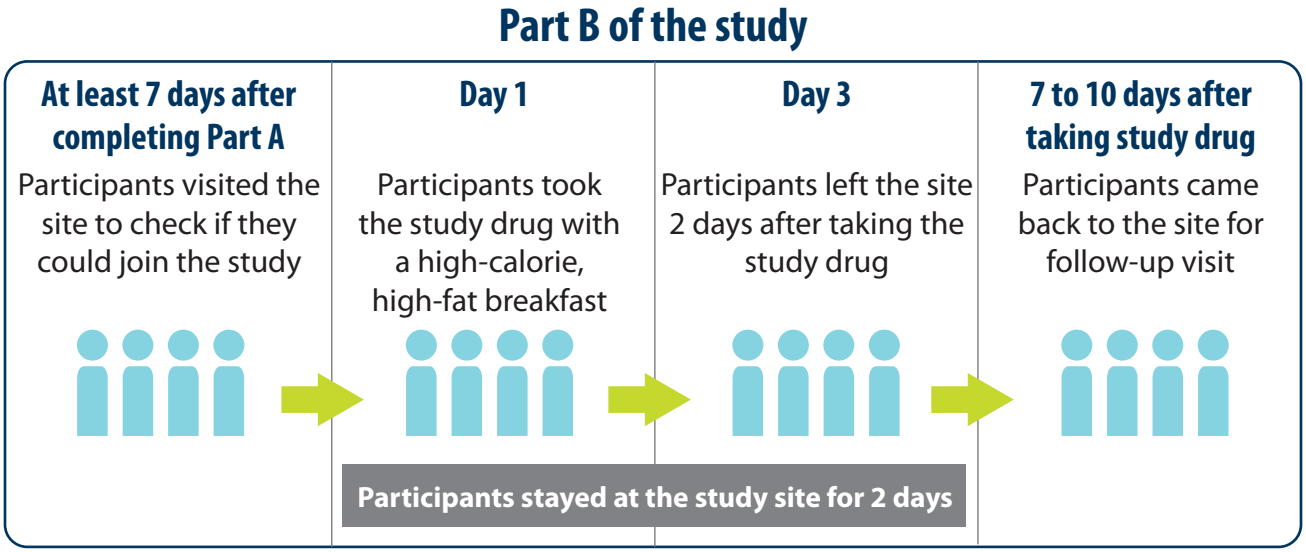
- 5 milligrams, or mg, AZD4831
- 15 mg AZD4831
- 45 mg AZD4831
- 135 mg AZD4831
- 405 mg AZD4831

The figure below shows how Part A of the study was done.



Part B started after Part A ended. During Part B, 4 participants who took the 45 mg dose of AZD4831 during Part A came back to the study site. Participants then took another 45 mg dose of AZD4831 with a high-calorie, high-fat breakfast on Day 1. Participants stayed at the study site for 2 days after taking the study drug on Day 1. Doctors at the study site took blood and urine samples every few hours after participants took the study drug. About 7 to 10 days after taking the study drug, participants came back to the study site for a follow-up visit.

The figure below shows how Part B of the study was done.



During both parts of study, study doctors did physical examinations and checked the blood pressure and heart rate of each participant. Study doctors did tests to check the heart health of participants and took samples of their blood and urine. Study doctors also asked participants about any medicines they were taking and how they were feeling.

What were the study results?

Below is a summary of the results of some of the questions researchers asked during the study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with AZD4831 are planned.

How did AZD4831 act in the body?

Researchers wanted to see how AZD4831 acted in the body when it was taken on an empty stomach and with food. Researchers wanted to know:

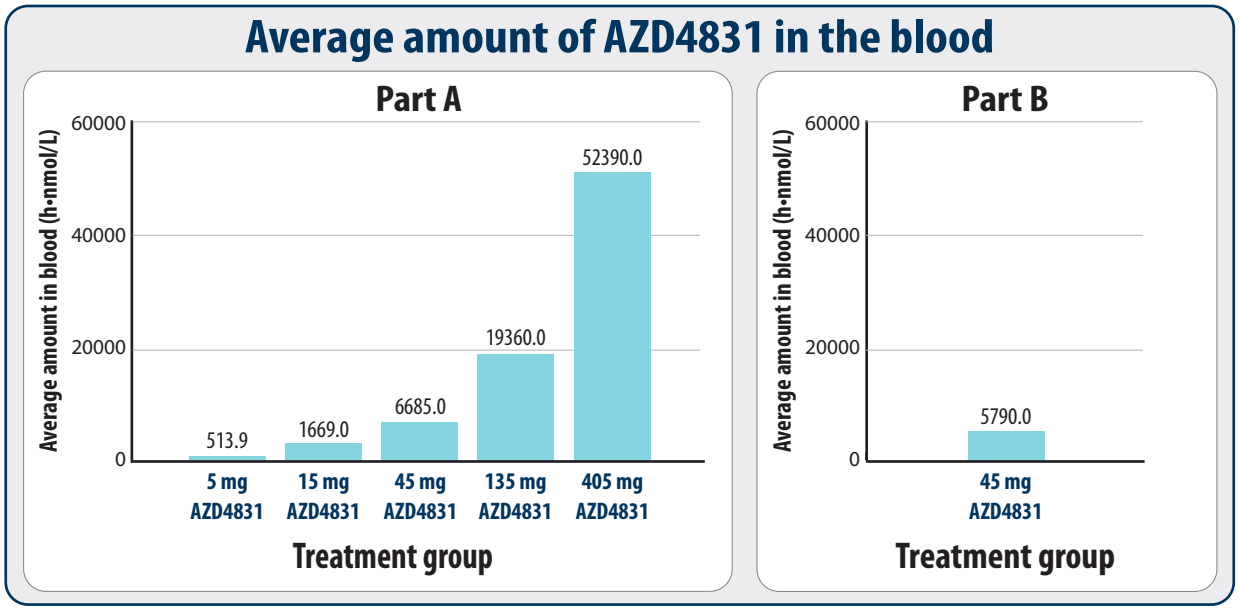
- The average amount of AZD4831 in the blood
- The highest amount of AZD4831 in the blood
- The time it took for AZD4831 to reach its highest amount in the blood

Overall, researchers found the following results:

- During Part A, AZD4831 was quickly taken up into the blood.
- Participants who took the higher doses of AZD4831 had higher average amounts of AZD4831 in the blood.
- During Part B, when taken with a high-calorie, high-fat breakfast, AZD4831 was taken up into the blood more slowly than in Part A. The amount of AZD4831 in the blood was a little lower in Part B than in Part A.

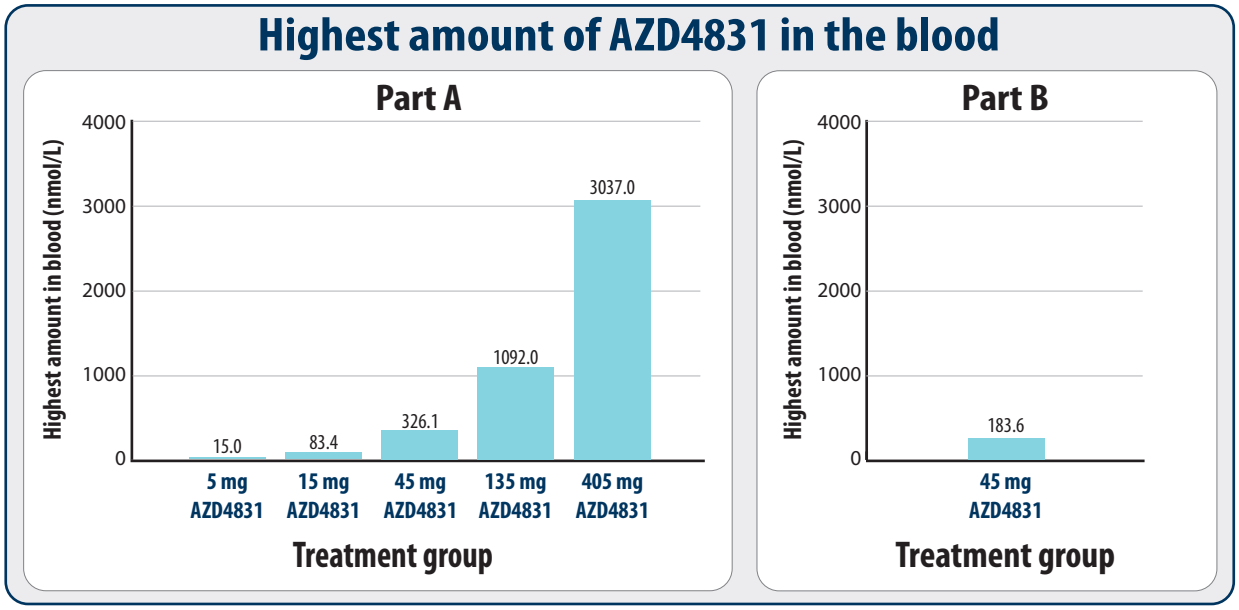
Average amount of AZD4831 in the blood

Researchers measured the average amount of AZD4831 in the blood in nanomoles each hour per liter of blood, or h•nmol/L. This is a way for researchers to measure the amount of study drug in participants' blood. The figures below show the average amount of AZD4831 in the blood for Part A and Part B of the study.



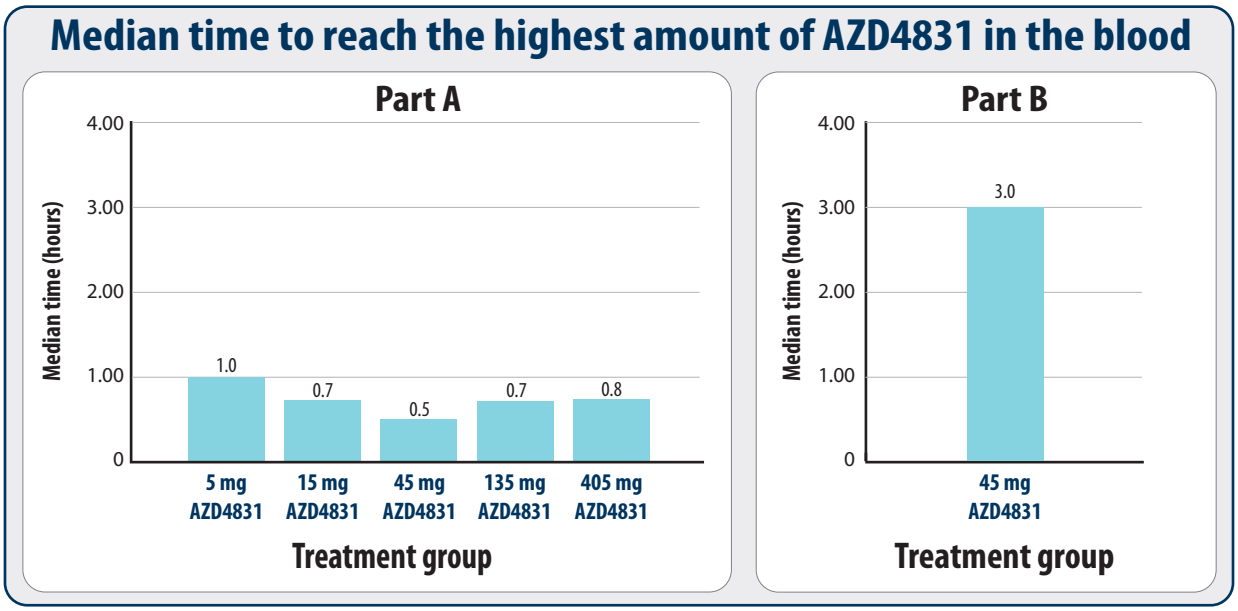
Highest amount of AZD4831 in the blood

Researchers also measured the highest amount of AZD4831 in the blood in nanomoles per liter of blood, or nmol/L. This is a way for researchers to measure the amount of study drug in participants' blood. The figures below show the average highest amount of AZD4831 in the blood for Part A and Part B of the study.



Time it took for AZD4831 to reach its highest amount in the blood

Researchers measured the median time in hours that it took for AZD4831 to reach its highest amount in the blood. The median is the amount of time halfway between the shortest time and the longest time it took for AZD4831 to reach the highest amount in the blood. The figures below show this time for Part A and Part B of the study.



What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem. 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.

How many participants had medical problems in the study?

In Part A, a similar percentage of participants taking AZD4831 and the placebo had medical problems. In Part B, no participants had medical problems. The table below shows how many participants in Part A of the study had medical problems. No participants stopped taking the study drug because of medical problems.

How many participants had medical problems in Part A of the study?

	Placebo (10 participants)	AZD4831 5 mg (6 participants)	AZD4831 15 mg (6 participants)	AZD4831 45 mg (6 participants)	AZD4831 135 mg (6 participants)	AZD4831 405 mg (6 participants)
How many participants had medical problems?	4 (40.0%)	2 (33.3%)	2 (33.3%)	3 (50.0%)	3 (50.0%)	2 (33.3%)

How many participants had serious medical problems?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospital care. In this study, no participants had serious medical problems, and no participants died.

What were the most common non-serious medical problems in the study?

The most common non-serious medical problems that participants had in this study were headache and a flat and raised rash on the skin. The table below shows the most common non serious medical problems that happened in Part A of the study.

Most common non-serious medical problems in Part A of the study

	Placebo (10 participants)	AZD4831 5 mg (6 participants)	AZD4831 15 mg (6 participants)	AZD4831 45 mg (6 participants)	AZD4831 135 mg (6 participants)	AZD4831 405 mg (6 participants)
Headache	4 (40.0%)	0 (0.0%)	1 (16.7%)	2 (33.3%)	1 (16.7%)	0 (0.0%)
Flat and raised rash on the skin	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	2 (33.3%)
Throat pain	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
Restlessness	1 (10.0%)	1 (16.7%)	0 (0.0)%	0 (0.0)%	0 (0.0)%	0 (0.0)%
Common cold	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)
Nosebleed	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Stomach illness	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)
Stuffy nose	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)

A total of 4 participants who took AZD4831 in Part A of the study had a flat and raised rash on the skin after taking the study drug. Study doctors thought the rashes could be caused by AZD4831. No participants had a rash after taking the placebo.

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 https://clinicaltrials.gov/ct2/show/NCT02712372.

Official study title: A Phase I, Randomized, Single-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of AZD4831 after Single and Multiple Ascending Dose Administration to Healthy Male Subjects

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 study. 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.

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.

CISCRP
One Liberty Square, Suite 510
Boston, MA 02109

1-877-MED-HERO
www.ciscrp.org