

Clinical Study Results



Research Sponsor: AstraZeneca AB

Drug Studied: AZD9977

Study Title: A study to learn how AZD9977 acts in the blood in healthy participants when taken with and without itraconazole

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD9977.

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 for you.

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 February 2019 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.

The study included 14 participants in the United States.

Why was the research needed?

Researchers are looking for a better way to treat heart failure. 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.

Heart failure is also called congestive heart failure or CHF. It can happen when certain medical conditions weaken the heart over time. As a result, the heart cannot pump blood through the body properly, and fluid builds up around the heart. AZD9977 is being developed as a possible treatment for CHF.

In this study, the researchers wanted to learn how AZD9977 acted in the blood when taken alone and when taken with a drug called itraconazole. Itraconazole is a common treatment used for fungal infections. Participants with CHF in future studies might take itraconazole at the same time as AZD9977 if they have a fungal infection. So, the researchers wanted to find out if taking these treatments together affected how much AZD9977 got into the blood.

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

- How much AZD9977 got into the participants' blood?
- 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 AZD9977 improves the health of people with CHF.

The researchers asked for the help of healthy men and women. Everyone in the study was 29 to 55 years old when they joined. The participants had no known heart or kidney problems.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participant knew what the participant was taking. In this study, all of the participants took AZD9977 and itraconazole capsules by mouth. The doses were measured in milligrams, also called mg. This study happened in 2 parts during 9 days.

In Part 1:

- On Day 1, all of the participants took 100 mg of AZD9977.
- On Days 2 and 3, the participants did not take any study treatment.

In Part 2:

- On Days 4, 5, 6, and 8, the participants took 200 mg of itraconazole.
- On Day 7, the participants took 1 dose each of 200 mg of itraconazole and 100 mg of AZD9977.

The participants took each of the study treatments after they had eaten breakfast.

What happened during the study?

Before the participants took study treatment, the doctors checked their overall health to make sure that they could join the study. This happened up to 28 days before the participants took the first treatment. The doctors:

- did a physical exam and checked the participants’ overall health
- took blood and urine samples
- checked the participants’ heart health using an electrocardiogram, also called an ECG

The doctors also checked the participants’ health and took blood and urine samples while the participants were taking treatment, and after their last treatment.

While the participants were taking treatment, they stayed at the study site for 9 days.

About 5 to 7 days after the last treatment, the participants visited the study site 1 time.

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.

How much AZD9977 got into the participants' blood?

The researchers wanted to know how much AZD9977 got into the blood when the participants took it alone compared to when they took it with itraconazole.

To answer this question, the study doctors measured the amount of AZD9977 in the participants' blood in Part 1 and in Part 2. They measured:

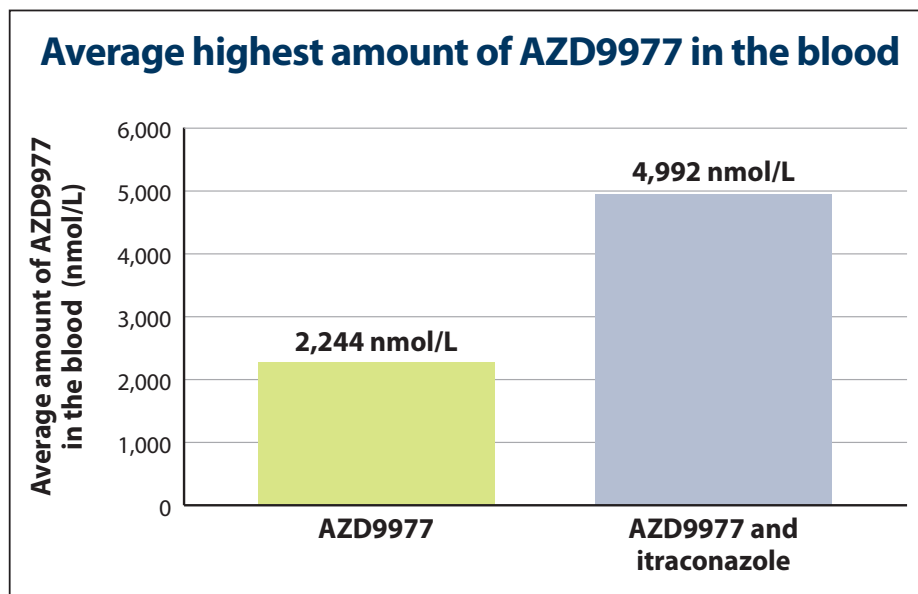
- the average highest amount of AZD9977
- the average total amount of AZD9977 over time
- the average total amount of AZD9977, up to the last blood sample taken during the study

Average highest amount of AZD9977

The average highest amount of AZD9977 was measured in units called nanomoles per liter, also known as nmol/L. The researchers found that the average highest amount of AZD9977 in the blood was:

- 2,244 nmol/L when AZD9977 was taken alone
- 4,992 nmol/L when AZD9977 was taken with itraconazole

The chart below shows these results.

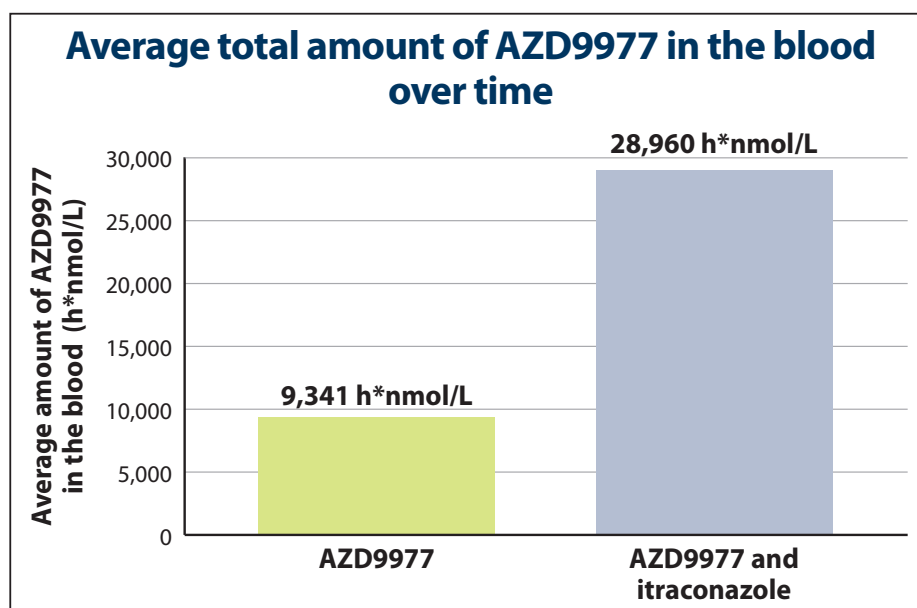


Average total amount of AZD9977 over time

The average total amount of AZD9977 over time was measured in units called nmol/L per hour, also known as h*nmol/L. The researchers found that the average total amount of AZD9977 over time in the blood was:

- 9,341 h*nmol/L when AZD9977 was taken alone
- 28,960 h*nmol/L when AZD9977 was taken with itraconazole

The chart below shows these results.

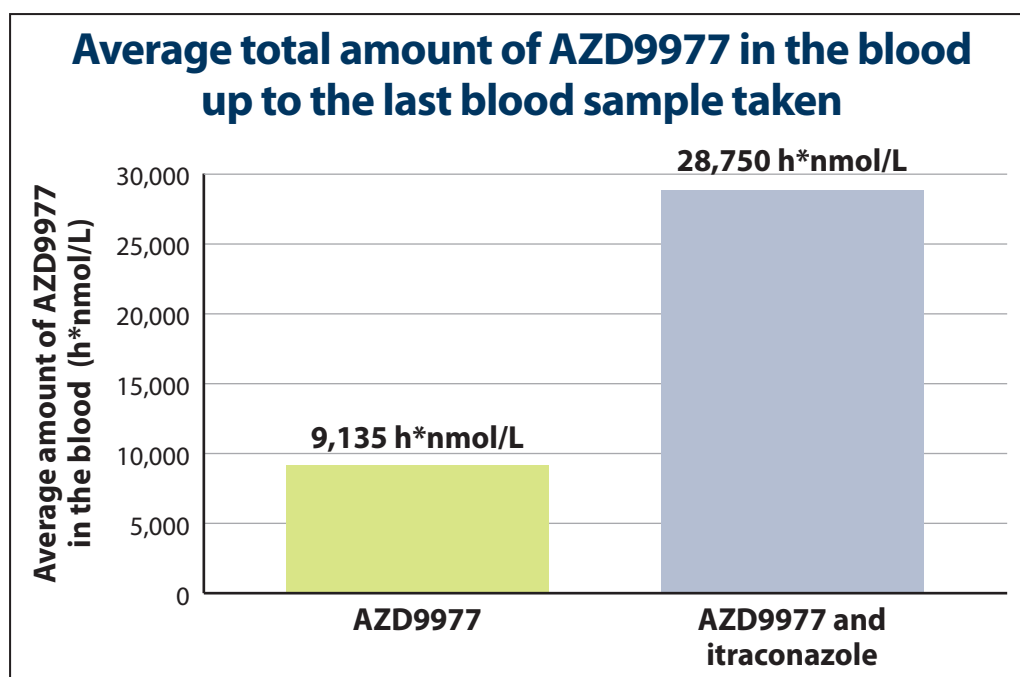


Average total amount of AZD9977 up to the last blood sample

The average total amount of AZD9977 was also calculated up to the last blood sample taken during the study. This was measured as h*nmol/L. The researchers found that the average total amount of AZD9977 in the blood up to the last blood sample in the study was:

- 9,135 h*nmol/L when AZD9977 was taken alone
- 28,750 h*nmol/L when AZD9977 was taken with itraconazole

The chart below shows these results.



What medical problems did the 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 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.

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.

How many participants had serious adverse reactions?

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

How many participants had adverse reactions?

None of the participants had adverse reactions during this study.

How has this study helped patients and researchers?

This study helped researchers learn how AZD9977 acts in the blood 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 AZD9977 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 “**NCT03843060**” into the search box, and click “**Search**”.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type “**D6401C00003**” into the search box, and click “**Find a Study**”.

Full Trial Title: A phase 1 single center open-label, non-randomized, fixed sequence study in healthy volunteers to assess the pharmacokinetics (PK) of AZD9977 when administered alone and with itraconazole

National Clinical Trials number: NCT03843060

AstraZeneca Protocol Number: D6401C00003

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.



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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