Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD9977

Study Title: A study to learn how different forms and doses of AZD9977 act in the body in healthy participants

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.

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. There were 2 parts to the study, called Part A and Part B.

The study included 12 participants in the United Kingdom.

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

Why was the research needed?

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 researchers in this study were looking for a better way to treat patients who have heart failure.

Heart failure is a condition in which the heart does not pump blood as well as it should. This can cause damage to the heart muscle and make the heart change shape. It can also cause fluid to build up in the arms and legs.

There are treatments for heart failure, but these may cause other medical problems in some patients. The study drug, AZD9977, was designed to work in a different way than current treatments.

In this study, the researchers wanted to find out how different forms and doses of AZD9977 act in the body, and if food affected this. They also wanted to learn if AZD9977 causes any medical problems.

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

- How did the different forms of AZD9977 act in the blood?
- How did AZD9977 act in the blood when taken with and without food?
- How did the different doses of AZD9977 act in the 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 who have heart failure.

The researchers asked for the help of healthy men. The participants in the study were 20 to 46 years old when they joined.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participant knew what treatment the participant took, and in what order.

The study had 2 parts, called Part A and Part B.

In Part A, the researchers wanted to compare how 4 different AZD9977 forms acted in the blood when taken without food. Based on these results, the researchers decided which form should be taken in Part B.

All 4 of the AZD9977 forms in Part A were taken by mouth. There were 3 different types of capsules, and 1 type of tablet. All of the participants in Part A took each of the AZD9977 forms, but in a different order. The doses of AZD9977 were measured in milligrams, also called mg.

In Part B, the researchers studied how 1 dose of AZD9977 acted in the blood when taken without food, and another dose of AZD9977 when taken with food. All of the participants in Part B took each of the doses of AZD9977 as a capsule, but in a different order.

During both parts, a computer program was used to randomly choose the order in which the participants took 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.

What happened during the study?

Before the participants took study treatment, they visited their study site 1 time. At this visit, the study doctors checked to make sure the participants could join the study. The study doctors:

- did a physical examination
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

Throughout the study, the researchers measured the amount of AZD9977 in the participants' blood. They also continued checking the participants' heart health and overall health, and asking them how they were feeling.

During Part A, the participants visited their study site 1 time and stayed there for 10 days. There were 4 different forms of AZD9977 in this part. The participants took each form 1 time. There was 1 tablet form, and 3 capsule forms: Capsule 1, Capsule 2, and Capsule 3. Each dose was 300 mg.

After the participants left their study site, there was a "washout period" of up to 5 weeks before Part B started. During this time, the participants did not take any study treatment. This was done so that each treatment could be "washed out" of their bodies.

During the washout period, the researchers studied the results from Part A. Based on these results, the researchers determined that the participants in Part B would take Capsule 1.

During Part B, the participants visited their study site 1 time and stayed there for 6 days. All of the participants took the 2 below forms:

- 50 mg of AZD9977 in Capsule 1 without food
- 300 mg of AZD9977 in Capsule 1 with food

About 1 week after Part B ended, the participants visited their study site 1 time. At this visit, the study doctors checked the participants' heart health and overall health, and asked them how they were feeling.

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 did the different forms of AZD9977 act in the blood?

To answer this question, the doctors took blood samples from the participants after they took each form of AZD9977 in Part A. They measured:

- the average total amount of AZD9977 in the blood over time
- the average amount of AZD9977 in the blood 24 hours after the participants took treatment
- the average total amount of AZD9977 in the blood, up to 24 hours after the participants took treatment
- the average total amount of AZD9977 in the blood, up to the last blood sample taken during the treatment
- the average highest amount of AZD9977 in the blood

Overall, the researchers found that these amounts were highest when the participants took 300 mg of AZD9977 in Capsule 1. So, the participants in Part B took this form.

How did AZD9977 act in the blood when taken with and without food?

To answer this question, the doctors did the same blood measurements in Part B as they did in Part A. The researchers compared the amounts of AZD9977 in the blood:

- after the participants took 300 mg of AZD9977 in Capsule 1 without food during Part A
- after the participants took 300 mg of AZD9977 in Capsule 1 with food during Part B

Overall, the researchers found that these amounts were higher when the participants took AZD9977 with food during Part B.

How did the different doses of AZD9977 act in the blood?

To answer this question, the researchers compared the amounts of AZD9977 in the blood:

- after the participants took 50 mg of AZD9977 in Capsule 1 without food in Part B
- after the participants took 300 mg of AZD9977 in Capsule 1 without food in Part A

Overall, the researchers found that these amounts were higher when the participants took 300 mg of AZD9977 compared to when they took 50 mg.

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 treatments. 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 treatments. A lot of research is needed to know whether a treatment 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 the study.

None of the participants died during the study.

How many participants had adverse reactions?

- There were 8.3% of participants who had adverse reactions during Part A of the study. This was 1 out of 12 participants. This participant had the adverse reaction of pain in the stomach area after taking 300 mg of AZD9977 in tablet form.
- None of the participants had adverse reactions during Part B of the study.
- None of the participants stopped treatment due to adverse reactions during the study.

How has this study helped patients and researchers?

This study helped researchers learn how different forms and doses of AZD9977 act in the body 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 **"NCT03804645"** into the search box, and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2018-004319-37"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6401C00006"** into the search box, and click **"Find a Study"**.

Full Trial Title: An Open-label, Randomized, Four-way Crossover Single Oral Dose Study Comparing the Pharmacokinetics of Four Different Formulations of AZD9977 (Part A) and Influence of Food and Lower Dose of a Selected Formulation (Part B) in Healthy Male Subjects

AstraZeneca AB Protocol Number: D6401C00006

AstraZeneca AB sponsored this study and has its headquarters at 151 85 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.

CISCRP

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 1100 • Boston, MA 02109
1-877-MED-HERO • www.ciscrp.org