Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD9977

Study Title: A study to learn about the safety of AZD9977 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 2018 and ended in June 2018. The study included 27 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?

Researchers are looking for a better way to treat patients with heart failure. Before a drug can be approved for patients to take, researchers do clinical studies to find out if it works and how safe it is.

In this study, the researchers wanted to find out about the safety of AZD9977 in healthy participants. They also wanted to find out if the participants had any medical problems during the study.

The study drug, AZD9977, is being developed to treat patients with heart failure.

In people with heart failure, 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. AZD9977 may help treat these medical problems, which may improve heart health.

In this study, the researchers wanted to learn more about the safety of 3 different AZD9977 doses.

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

- Did the participants' safety results change during the study?
- 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 patients with heart failure.

The researchers asked for the help of healthy men. The participants in the study were 23 to 45 years old when they joined.

What kind of study was this?

This was a "single-blind" study. This means the researchers knew what the participants were taking, but the participants did not.

There were 3 treatment groups in this study. In each group, the participants took either AZD9977 or a placebo. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to make sure any of the effects they see in the participants who take a drug are actually caused by that drug.

A computer program was used to randomly choose the treatment each participant took. 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.

This was also a "dose-escalation" study. This means that each group got only 1 dose amount of AZD9977 during the study. Researchers use dose-escalation treatments so they can study the effects and safety of a drug dose before increasing the dose for other participants.

In this study, different groups of participants were given different doses of AZD9977. The researchers carefully studied the results from each group before deciding whether or not to give the next higher dose to the next group of participants.

What happened during the study?

Before treatment, the participants visited their study site 1 time. During this visit, the study doctors:

- did tests and physical exams to make sure the participants could join the study
- asked the participants how they were feeling
- checked the participants' heart health using an electrocardiogram, also called an ECG

During treatment, the participants visited their study site 1 time and stayed there for 11 days. The participants took their study treatment on 8 of these 11 days. They took either AZD9977 or the placebo as a liquid by mouth. The doses of AZD9977 were measured in milligrams, also called mg.

The table below shows the treatments the participants took.

6 participants took 50 mg of AZD9977	All 27 participants took their study treatment: 1 time on the first and eighth day 2 times a day on the second through seventh days
6 participants took 150 mg of AZD9977	
6 participants took 300 mg of AZD9977	
9 participants took the placebo	

Throughout treatment, the study doctors checked the overall health and heart health of the participants and asked them how they were feeling.

After treatment, the participants visited their study site 1 time about 1 week after they took their last treatment. At this visit, the study doctors checked the overall health and heart health of the participants 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.

Did the participants' safety results change during the study?

No. Overall, the participants' safety results did not change during the study.

To answer this question, the researchers performed tests throughout the study. Then, they compared the results for the participants who took AZD9977 to the results for the participants who took the placebo. The study doctors:

- performed physical examinations and checked participants' vital signs
- took blood and urine samples from the participants
- checked participants' heart health using an ECG

Overall, the participants who took AZD9977 and the participants who took the placebo had some changes in their test results during the study. But, these changes were too small for the researchers to consider them meaningful.

What medical problems did the participants have during the study?

To answer this question, the researchers recorded any medical problems the participants had during the study. These medical problems are called "adverse events". An adverse event is any medical problem that happens during the study. Adverse events are considered "serious" when they are life-threatening, cause lasting problems, or require hospital care. Adverse events may or may not be caused by the study drug.

What serious adverse events did participants have?

None of the participants had serious adverse events during the study.

None of the participants died during the study.

How many participants had adverse events?

There were 22.2% of participants who took AZD9977 who had adverse events during the study. This was 4 out of 18 participants.

There were 66.7% of participants who took the placebo who had adverse events during the study. This was 6 out of 9 participants.

None of the participants stopped treatment because of adverse events they had during the study.

The table below shows how many participants had adverse events during the study.

Adverse events during the study

	AZD9977 50 mg (out of 6 participants)	AZD9977 150 mg (out of 6 participants)	AZD9977 300 mg (out of 6 participants)	Placebo (out of 9 participants)
How many participants had adverse events during the study?	33.3% (2)	16.7% (1)	16.7% (1)	66.7% (6)
How many participants had serious adverse events during the study?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment because of adverse events?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

What adverse events did the participants have?

The most common adverse event was headache.

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

Most common adverse events during the study

	AZD9977 50 mg (out of 6 participants)	AZD9977 150 mg (out of 6 participants)	AZD9977 300 mg (out of 6 participants)	Placebo (out of 9 participants)
Headache	16.7% (1)	0.0% (0)	0.0% (0)	22.2% (2)
Skin rash	0.0% (0)	0.0% (0)	0.0% (0)	22.2% (2)
Bacterial skin infection	16.7% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Back pain	0.0% (0)	16.7% (1)	0.0% (0)	0.0% (0)
Dizziness	0.0% (0)	16.7% (1)	0.0% (0)	0.0% (0)
Chest pain	0.0% (0)	0.0% (0)	16.7% (1)	0.0% (0)
Discomfort in ear	0.0% (0)	0.0% (0)	16.7% (1)	0.0% (0)
Congestion in nose	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)
Seasonal allergy	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)
Swelling in the body	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)

What adverse reactions did the participants have during the study?

This section is a summary of the adverse events 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 the study.

How many participants had adverse reactions?

There were 5.6% of participants who took AZD9977 who had adverse reactions during the study. This was 1 out of 18 participants.

There were 22.2% of participants who took the placebo who had adverse reactions during the study. This was 2 out of 9 participants.

None of the participants stopped treatment because of adverse reactions they had during the study.

The table below shows how many participants had adverse reactions during the study.

Adverse reactions during the study

	AZD9977 50 mg (out of 6 participants)	AZD9977 150 mg (out of 6 participants)	AZD9977 300 mg (out of 6 participants)	Placebo (out of 9 participants)
How many participants had adverse reactions during the study?	16.7% (1)	0.0% (0)	0.0% (0)	22.2% (2)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment because of adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions did the participants have?

The only adverse reaction that happened during the study was headache. This adverse reaction happened in:

- 16.7% of participants who took 50 mg of AZD9977. This was 1 out of 6 participants.
- 22.2% of participants who took the placebo. This was 2 out of 9 participants.

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of AZD9977 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.

Other 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 "**NCT03435276**" into the search box, and click "**Search**".
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2017-004619-38"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6401C00001"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase 1, Randomized, Placebo-controlled Study to Assess the Safety, Tolerability and Pharmacokinetics of AZD9977 Following Multiple-Ascending Dose Administration in Healthy Volunteers

AstraZeneca Protocol Number: D6401C00001

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.

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.

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