Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca AB

Drug Studied: AZD9977

Study Title: A study to learn about the safety of AZD9977 in healthy Japanese 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 January 2019 and ended in May 2019. It included 28 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 who have 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 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 learn about the safety of different doses of AZD9977 in healthy participants.

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 people who have heart failure.

The researchers asked for the help of healthy Japanese men. The participants in this study were 22 to 49 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. This was also a "dose-escalation" study. This means that the participants who took AZD9977 took only 1 dose amount of the drug 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, the participants took either AZD9977 or a placebo as a liquid by mouth. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the drug are actually caused by the drug. The AZD9977 doses were measured in milligrams, also called mg.

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.

What happened during the study?

Before treatment, the participants visited their study site 1 time over the course of about 4 weeks. At this visit, the study doctors checked to make sure the participants could join the study. The study doctors:

- did a physical examination and checked the participants' vital signs
- 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

During the study, the participants visited their study site 1 time and stayed there for 12 days. During this time, they took either AZD9977 or a placebo. The first group of participants who took AZD9977 started out taking a low dose. Then, the researchers carefully studied the results for those participants before deciding to increase the dose in the next group of participants.

There were 4 treatment groups in the study. Each group took 14 doses of 1 of the below treatments:

- 7 participants took 50 mg of AZD9977
- 6 participants took 150 mg of AZD9977
- 6 participants took 300 mg of AZD9977
- 9 participants took a placebo

Throughout the study, the researchers continued checking the participants' heart health and overall health, and asking them how they were feeling.

About 1 week after taking their last treatment, 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.

Did the participants' safety results change during the study?

To answer this question, the researchers compared the results of the tests and measurements that were done before the participants took treatment to the results throughout the study.

Overall, the researchers found that there were some changes in the participants' results during the study. But these changes were too small for the researchers to consider them to be significant.

The doctors also kept track of the "adverse events" that the participants had during the study. An adverse event is any sign or symptom that participants have during a study.

Doctors keep track of all of the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment. An adverse event is considered "serious" when it is life threatening, causes lasting problems, or the participant needs hospital care. Adverse events may or may not be caused by the treatments in the study.

The websites listed at the end of this summary may have more information about the adverse events that happened during this study.

Serious adverse events

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

None of the participants died during the study.

Adverse events

There were 31.6% of participants who had adverse events after taking AZD9977 during the study. This was 6 out of 19 participants.

There were 55.6% of participants who had adverse events after taking the placebo during the study. This was 5 out of 9 participants.

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

Adverse events during the study

	50 mg of AZD9977 (Out of 7 participants)	150 mg of AZD9977 (Out of 6 participants)	300 mg of AZD9977 (Out of 6 participants)	Placebo (Out of 9 participants)
How many participants had adverse events during the study?	28.6% (2)	16.7% (1)	50.0% (3)	55.6% (5)
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 due to adverse events?	14.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)

Adverse events

The most common adverse events during the study were skin rash and increase in the levels of enzymes called transaminases in the body. This is a possible sign that the liver is not working as well as it should.

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

Adverse events during the study

	50 mg of AZD9977 (Out of 7 participants)	150 mg of AZD9977 (Out of 6 participants)	300 mg of AZD9977 (Out of 6 participants)	Placebo (Out of 9 participants)
Increase in levels of enzymes called transaminases in the body (a possible sign that the liver is not working as well as it should)	0.0% (0)	0.0% (0)	33.3% (2)	11.1% (1)
Skin rash	0.0% (0)	0.0% (0)	16.7% (1)	22.2% (2)
Diarrhea	14.3% (1)	16.7% (1)	0.0% (0)	0.0% (0)
Dry lips	14.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Feeling congested	14.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Formation of pus around a tooth caused by an infection	14.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Pain in the face	14.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Dry eyes	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)
Feeling drowsy	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)
Stomach discomfort	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)

What medical problems 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 adverse events are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

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 adverse reactions listed in this section are also included in the list of adverse events above.

The websites listed at the end of this summary may have more information about the adverse reactions 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 5.3% of participants who had adverse reactions after taking AZD9977 during the study. This was 1 out of 19 participants.

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

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

Adverse reactions during the study

	50 mg of AZD9977 (Out of 7 participants)	150 mg of AZD9977 (Out of 6 participants)	300 mg of AZD9977 (Out of 6 participants)	Placebo (Out of 9 participants)
How many participants had adverse reactions during the study?	0.0% (0)	16.7% (1)	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 due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions did the participants have?

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

Adverse reactions during the study

	50 mg of AZD9977 (Out of 7 participants)	150 mg of AZD9977 (Out of 6 participants)	300 mg of AZD9977 (Out of 6 participants)	Placebo (Out of 9 participants)
Diarrhea	0.0% (0)	16.7% (1)	0.0% (0)	0.0% (0)
Feeling drowsy	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)
Stomach discomfort	0.0% (0)	0.0% (0)	0.0% (0)	11.1% (1)

How has this study helped patients and researchers?

This study helped researchers learn about the safety of different doses of AZD9977 when taken by healthy Japanese men.

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 **"NCT03801967"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6401C00005"** into the search box, and click **"Find a Study"**.

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

AstraZeneca AB Protocol Number: D6401C00005

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.

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