Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD6094

Study Title: A study to learn how a drug called AZD6094 affects the electrical activity of the hearts of healthy volunteers

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug AZD6094.

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 September 2017 and ended in March 2018. The study included 45 participants in the United States.

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 solid tumors in patients with certain types of cancer. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

Patients with solid tumors have a type of cancer in their bones, muscles, or organs that does not contain any liquid areas. Researchers think the study drug AZD6094 can help treat these tumors in the lungs and kidneys by stopping them from growing.

In this study, the researchers wanted to learn how AZD6094 affects the electrical activity of the heart. The electrical activity of the heart controls how fast or slow the heart beats. Changes to the electrical activity of the heart can cause heartbeats to either speed up or slow down. These changes can be dangerous, or even life-threatening.

Researchers compared AZD6094 to a placebo and to another drug called moxifloxacin. A placebo looks like the study 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 a treatment are actually caused by that treatment.

Moxifloxacin is an antibiotic that is already approved for use. But, it affects the electrical activity of the heart. In this study, participants took moxifloxacin so that the electrical activity of the heart could be looked at by using a medicine that is known to affect it. The effects of moxifloxacin were looked at but are not included as part of the study results.

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

- Did AZD6094 affect the electrical activity of the heart?
- 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 AZD6094 improves the health of people with solid tumors.

The researchers asked for the help of healthy male volunteers. Everyone in the study was 33 to 64 years old when they joined.

What kind of study was this?

This was a “double-blind” study. This means none of the participants or the researchers knew which treatment the participants took in each treatment period. Some studies are done this way because knowing what treatment the participants are getting can affect the results of the study. When the study ended, the research sponsor found out which treatment each participant took in each treatment period so they could create a report of the study results.

During the study, participants took either AZD6094, placebo, or moxifloxacin during each treatment period. A computer program was used to randomly choose the order each participant took these treatments. This helps make sure the treatments 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 started treatment, the doctors checked their overall health and their heart health to make sure they could join the study. The doctors:

- asked about the medical history of the participants, how they were feeling, and what medicines they were taking
- checked the heart health of participants by doing a test called an electrocardiogram, also known as an ECG, which is a recording of the heart’s rhythm
- took blood and urine samples
- did a physical examination

During the study, the participants visited the study site 3 times. At each visit, the participants checked in to the study site the day before taking their assigned treatment. They stayed at the site for at least 3 nights per visit. During each visit, the doctors checked their overall health and their heart health as they did before.

Participants took 1 of the study treatments during each visit. Each visit was 14 days apart. This allowed for any treatment that the participants were taking to be “washed out” of their bodies before they continue taking the other treatments in this study.

All treatments were taken by mouth. Doses were measured in milligrams, also called mg. Participants took each of the following treatments once, but in different orders:

- 3 tablets of 200 mg AZD6094, for a total of 600 mg AZD6094
- 3 tablets of placebo that looked like AZD6094
- 1 capsule of 400 mg moxifloxacin

At the end of the study, the participants returned to the study site for a follow-up visit. During this visit, the doctors checked their overall health and their heart health again.

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 AZD6094 affect the electrical activity of the heart?

Yes. On average, the participants who took the single dose of 600 mg AZD6094 had the electrical activity of the heart slow down.

The researchers looked at the participants' ECG test results to find out how AZD6094 affected the electrical activity of the heart. The participants had an ECG done 15 minutes before each dose of study treatment. Then they had 12 more ECGs done every 30 minutes and then every few hours until 48 hours after each dose of study treatment.

Researchers found that 3 to 6 hours after taking AZD6094, the electrical activity of the heart may be slowed down by more than 10 milliseconds compared to the placebo.

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 drugs. 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 drugs. 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 a serious adverse reaction.

How many participants had adverse reactions?

There were 2.2% of the participants who had adverse reactions when taking the placebo during the study. This was 1 out of 45 participants. This adverse reaction was a rapid heartbeat that happened once during the study.

None of the participants who took AZD6094 had an adverse reaction.

None of the participants left the study or stopped taking AZD6094 because of adverse reactions

How has this study helped participants and researchers?

These results helped the researchers determine the effects of the study drug AZD6094. This will help them make decisions related to using AZD6094 in the care of patients with cancerous solid tumors.

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 1 study. Other studies may provide new information or different results.

Further clinical studies with AZD6094 are ongoing and 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 **"NCT03258515"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5084C00001"** into the search box and click **"Find a Study"**.

Full trial title: A Single-center, Randomized, Double-blind, Placebo-controlled, Three-way Crossover Phase I study to Investigate the Effect on the QTc Interval of a Single Dose of AZD6094 (600 mg) Compared with Placebo, Using Open-label Moxifloxacin (Avelox®) as a Positive Control, in Healthy Volunteers

AstraZeneca Protocol number: D5084C00001

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 participants.