Clinical Study Results

Research Sponsor: AstraZeneca

Drug Studied: AZD1390

Study Title: A study to learn if AZD1390 can enter the brains of healthy participants

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug AZD1390.

AstraZeneca 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 October 2017 and ended in January 2018.

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 brain tumors. Brain tumors are cancer cells that grow in the brain. Before a drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

The brain is protected by blood vessels that make up the blood-brain barrier, also called the BBB. The BBB lets some treatments into the brain, but keeps others out. If a treatment cannot cross the BBB and enter the brain, it might not work. Researchers think that treatments that can cross the BBB may help treat illnesses in the brain.

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

- Did AZD1390 enter the brains of healthy participants?
- Did the participants have any medical problems during the study?

The answers to these questions are important to know before other studies can be done that help find out if AZD1390 can improve the health of people with brain tumors.

To answer these questions, the researchers asked for the help of healthy participants who did not have brain tumors.

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.

All the participants got one very small dose of AZD1390. AZD1390 was specially prepared to give off a small amount of radiation so that it could be measured in the body for up to 2 hours after it was given. The participants got AZD1390 through a needle placed into a vein. This is called an intravenous infusion, also known as an IV.

What happened during the study?

Before the study started, the researchers:

- checked the participants’ health to make sure they could join the study
- asked participants about their medical history, how they were feeling, and what medicines they were taking
- gave each participant a test called magnetic resonance imaging, also called an MRI, to make sure that their brain was healthy before joining the study

During the study, the participants visited their study site once. During this visit:

- The participants got 1 dose of AZD1390 through an IV.
- The researchers took pictures of each participant’s brain using positron emission tomography, also called a PET scan. By using the PET scan, doctors could see if AZD1390 entered the participant’s brain.
- After getting AZD1390 and during the PET scan, the researchers took blood samples. Blood samples were taken from a needle placed in an artery in the opposite arm of where AZD 1390 was given in a vein.

At the end of the study, a follow-up phone call was done about 7 days after the participant got the treatment and the PET scan. This was done to ask each participant about their health and 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 decisions.

The websites listed at the end of this summary may have a full report of the study results.

Did AZD1390 enter the brain of healthy participants?

Yes. The researchers found that AZD1390 crossed the BBB and entered the participants' brains. To answer this question, the researchers studied the participants' PET scans, which showed that AZD1390 had entered the brain.

Did the participants have any medical problems during the study?

The medical problems participants have during clinical studies that the researchers think might be related to the study drug are called "adverse reactions". An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study 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.

None of the participants in this study had adverse reactions related to the small dose of drug that was given or to the PET scans. The websites listed at the end of this summary may have other information about medical problems that happened in this study.

How has this study helped patients and researchers?

This study helped researchers learn more about AZD1390 and that it enters the brains of 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 1 study. Other studies may provide new information or different results.

Another study is now taking place in patients with brain tumors to see if bigger doses of AZD1390 are safe and can help treat the disease. Further clinical studies with AZD1390 may be 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 also can be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03215381"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home & Search"**, then type **"2017-002357-11"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6940C00001"** into the search box and click **"Find a Study"**.

Full Trial Title: An Open-Label Positron Emission Tomography Study to Determine Brain Exposure of AZD1390 after Intravenous Administration of a microdose [^{11}C]AZD1390 to Healthy Volunteers

AstraZeneca Protocol Number: D6940C00001

AstraZeneca sponsored this study and has its headquarters at 1800 Concord Pike in Wilmington, Delaware.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you!

Clinical trial 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.