Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD7594

Study Title: A study to learn how AZD7594 acts in the body

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD7594. 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 June 2019 and ended in July 2019. It included 6 participants.

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 people who have asthma. 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.

Asthma is a condition that causes the airways to narrow, swell, and create extra mucus. This can cause symptoms such as wheezing, coughing, and difficulty breathing.

There are several treatments that doctors use to help people manage their asthma symptoms. But these treatments may not work for some people, and may cause medical problems.

The study drug, AZD7594, is being developed to help people who have asthma control their asthma symptoms. In this study, the researchers wanted to find out how the body gets rid of AZD7594, and how AZD7594 acts in the body.

There were 2 forms of AZD7594 in this study: an inhaled form, and a form given through a needle into a vein. This second form is known as intravenous treatment, also called IV treatment.

The researchers in this study added a “tracer” to the IV form of AZD7594. Researchers use tracers to keep track of a study drug as it moves throughout the body. Tracers allow researchers to better understand how a drug acts in the body, and how the body gets rid of the drug.

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

- How did the IV tracer leave the body?
- How did the 2 forms of AZD7594 act in the body?
- 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 AZD7594 improves the health of people who have asthma.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participant knew what treatment the participant was getting.

In this study, the participants got 2 forms of AZD7594. All of the participants got these forms in the same order. The first form was given through an inhaler. The second form was combined with a tracer and given through an IV.

The AZD7594 doses were measured in micrograms, also called µg.

What happened during the study?

Before getting 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 about 1 week. During this time, they got both of the below treatments 1 time:

- 720 µg of AZD7594 through an inhaler
- 30 µg of AZD7594 with a tracer through an IV

Throughout the study and before the participants left their study site, the researchers continued checking the participants’ overall health and asking them how they were feeling. They also took blood, urine, and feces samples.

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 IV tracer leave the body?

To answer this question, the researchers measured how much of the tracer was in the participants' urine and feces after the participants got the IV treatment of AZD7594. Then, they compared the results.

The researchers studied:

- the amount of the tracer in the urine and feces
- the percentage of the tracer in the urine and feces

Overall, the researchers found that both the amount and percentage of the tracer were higher in the feces compared to the urine.

How did the 2 forms of AZD7594 act in the body?

To answer this question, the researchers measured the amount of AZD7594 in the blood after the participants got both the inhaled and IV forms of AZD7594. Then, they compared the results.

The researchers measured:

- the total amount of AZD7594 in the blood during the study
- the total amount of AZD7594 in the blood at the end of the study
- the highest amount of AZD7594 in the blood during the study

Overall, the researchers found that after the participants got both forms of AZD7594:

- The total amount of AZD7594 in the blood during the study was higher for the inhaled form compared to the IV form.
- The total amount of AZD7594 in the blood at the end of the study was higher for the inhaled form compared to the IV form.
- The highest amount of AZD7594 in the blood during the study was higher for the IV form compared to the inhaled form.

What medical problems did the participants have during the study?

The medical problems that the participants had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps to protect their identities.

The medical problems participants have during clinical studies that the doctors 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.

How has this study helped patients and researchers?

This study helped researchers learn more about how AZD7594 acts in the body.

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 AZD7594 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 **"NCT04002427"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D3741C00010"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase I, Open-Label Study to Assess Mass Balance Recovery, Pharmacokinetics, Metabolite Profile and Metabolite Identification after Intravenous Administration of [14C]AZD7594 and Inhaled Administration of AZD7594 in Healthy Subjects

AstraZeneca AB Protocol Number: D3741C00010

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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