

Clinical Study Results



Research Sponsor: AstraZeneca AB

Drugs Studied: AZD7594

Study Title: A study to learn how 2 different forms of AZD7594 act 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 study doctor or staff at your study site.

Who took part in the study?

The researchers asked for the help of healthy men and women. The participants were 18 to 54 years old when they joined.

The study included 24 participants in Germany.

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 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 makes it difficult to breathe. People who have asthma may wheeze, cough, and have shortness of breath.

There are treatments that can help people manage their asthma symptoms. But, these treatments may not help some people control their asthma symptoms. They may also cause medical problems.

The study drug, AZD7594, is an inhaled asthma treatment. Researchers think that AZD7594 may help people who have asthma to better manage their symptoms.

In this study, the researchers wanted to learn how AZD7594 acted in the body when taken through 2 different types of inhalers.

What was the purpose of this study?

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

- How did AZD7594 act in the participants' bodies?
- What medical problems happened during the study?

The answers to these questions are important to know before other studies can be done to find out if AZD7594 helps improve the health of people who have asthma.

What treatments did the participants take?

This was an “open-label” study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

In this study, the participants took 3 inhaled treatments of AZD7594, but in a different order. Two of the treatments were taken through a nebulizer, which is used to inhale treatments into the lungs in mist form. The other treatment was taken through a dry powder inhaler, also called a DPI. DPIs are used to inhale treatments into the lungs in powder form.

The nebulizer doses were measured in milligrams, also called mg. The DPI dose was measured in micrograms, also called μg .

A computer program was used to randomly choose the order in which the participants took each treatment. 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.

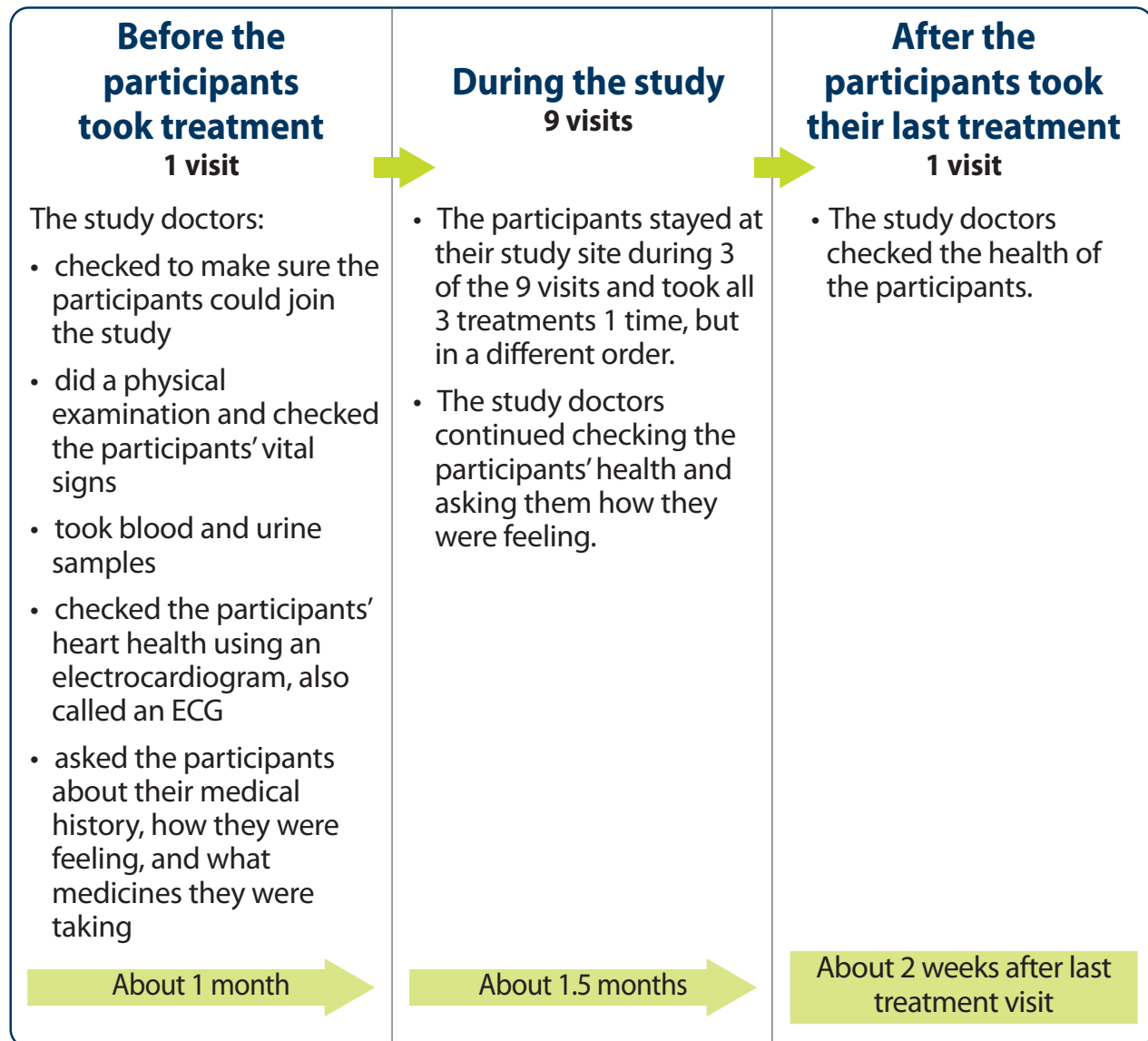
The chart below shows the treatments the participants took.

Treatment dose	Type of inhaler
0.7 mg of AZD7594	Nebulizer
1.6 mg of AZD7594	Nebulizer
720 μg of AZD7594	DPI

What happened during the study?

The study started in September 2019 and ended in November 2019.

The chart below shows how the study was done.



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 more information about the study results.

How did AZD7594 act in the participants' bodies?

To answer this question, the researchers measured the amount of AZD7594 in the blood when the participants took the 3 inhaled treatments.

The researchers measured:

- The amount of AZD7594 in the participants' blood while taking treatment
- The amount of AZD7594 in the participants' blood up to 4 days after taking treatment
- The highest amount of AZD7594 in the participants' blood while taking treatment

Then, they compared these amounts from when the participants took the nebulizer treatments to when they took the DPI treatment.

The researchers compared:

- The 0.7 mg AZD7594 nebulizer to the 720 µg AZD7594 DPI
- The 1.6 mg AZD7594 nebulizer to the 720 µg AZD7594 DPI

Overall, the researchers found that these amounts were highest when the participants took 1.6 mg of AZD7594 through a nebulizer. The researchers also found that overall, these amounts were lowest when the participants took 0.7 mg of AZD7594 through a nebulizer.

The 0.7 mg AZD7594 nebulizer compared to the 720 µg AZD7594 DPI

Overall, the researchers found that:

- The amount of AZD7594 in the participants' blood while taking treatment was similar when they took the 0.7 mg AZD7594 nebulizer compared to when they took the 720 µg AZD7594 DPI.
- The amount of AZD7594 in the participants' blood up to 4 days after taking treatment was lower when they took the 0.7 mg AZD7594 nebulizer compared to when they took the 720 µg AZD7594 DPI.
- The highest amount of AZD7594 in the participants' blood while taking treatment was similar when they took the 0.7 mg AZD7594 nebulizer compared to when they took the 720 µg AZD7594 DPI.

The 1.6 mg AZD7594 nebulizer compared to the 720 µg AZD7594 DPI

Overall, the researchers found that:

- The amount of AZD7594 in the participants' blood while taking treatment was higher when they took the 1.6 mg AZD7594 nebulizer compared to when they took the 720 µg AZD7594 DPI.
- The amount of AZD7594 in the participants' blood up to 4 days after taking treatment was higher when they took the 1.6 mg AZD7594 nebulizer compared to when they took the 720 µg AZD7594 DPI.
- The highest amount of AZD7594 in the participants' blood while taking treatment was higher when they took the 1.6 mg AZD7594 nebulizer compared to when they took the 720 µg AZD7594 DPI.

What medical problems happened 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 treatments. 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 treatments. A lot of research is needed to know whether a treatment causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for these treatments.

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.

Did any adverse reactions happen during this study?

There were 8.3% of participants who had adverse reactions during this study. This was 2 out of 24 participants.

None of the participants had serious adverse reactions during this study.

None of the participants died during this study.

The table below shows how many participants had adverse reactions.

Adverse reactions during this study			
	0.7 mg of AZD7594 through a nebulizer (out of 24 participants)	1.6 mg of AZD7594 through a nebulizer (out of 24 participants)	720 µg of AZD7594 through a DPI (out of 24 participants)
How many participants had adverse reactions?	4.2% (1)	0.0% (0)	4.2% (1)
How many participants had serious adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)
How many participants left this study due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions happened during this study?

There were 2 adverse reactions that happened during this study:

- A reduced sense of taste. This happened in 4.2% of participants, which was 1 out of 24 participants. This adverse reaction happened while this participant was taking 0.7 mg of AZD7594 through a nebulizer.
- Vertigo, which is a condition in which a person feels they are in motion even though they are not. This happened in 4.2% of participants, which was 1 out of 24 participants. This adverse reaction happened while this participant was taking 720 µg of AZD7594 through a DPI.

How has this study helped patients and researchers?

This study helped researchers learn how 2 different forms of AZD7594 act 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 more information about the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type “**NCT04072562**” into the search box, and click “**Search**”.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type “**D3742C00001**” into the search box, and click “**Find a Study**”.

Full Trial Title: An Open-label, Single-centre, Randomised, 3-period, 3-treatment, Single-dose, Crossover Study to Assess the Relative Bioavailability of AZD7594 Inhaled via a Nebulizer and via a Dry Powder Inhaler in Healthy Subjects

AstraZeneca Protocol Number: D3742C00001

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.



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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