

Research Sponsor: AstraZeneca AB

Drug Studied: AZD7594

Study Title: A study to learn how AZD7594 acts in the blood of adolescents with asthma

Protocol Number: D3741C00012

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 or your child 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 adolescents with asthma. The participants in this study were 12 to 17 years old when they joined.

The study included 36 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 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 treatments that can help people manage their asthma symptoms. But, these treatments may not help some people. They may also cause medical problems.

The study drug, AZD7594, was developed as an inhaled asthma treatment. In this study, the researchers wanted to learn how AZD7594 acted in the participants' blood. They also wanted to find out if the participants had any medical problems during the study.

This information may help researchers to set doses in adolescents, and help future researchers to determine which doses of AZD7594 to give to future study participants.



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 blood?
- > 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 improves the health of people who have asthma.

The answers to these questions are important to learn more about how AZD7594 works.



What treatments did the participants take?





All of the participants took the same dose of AZD7594 through an inhaler. The doses were measured in micrograms, also called µg.

If the participants' asthma got worse at any time during the study, they could take a "rescue medicine". This was a medicine chosen by the study doctors that the participants could take to help manage their asthma. The rescue medicines in this study were salbutamol or albuterol.

There were 2 groups of participants in this study. The first group included participants who were 12 to 14 years old. The second group included participants who were 15 to 17 years old.

This was an "open-label" study. This means the participants and their caregivers knew what treatment the participants were taking. The researchers, study doctors, and other study staff also knew what treatment each participant was taking.

The chart below shows the treatments the participants took.

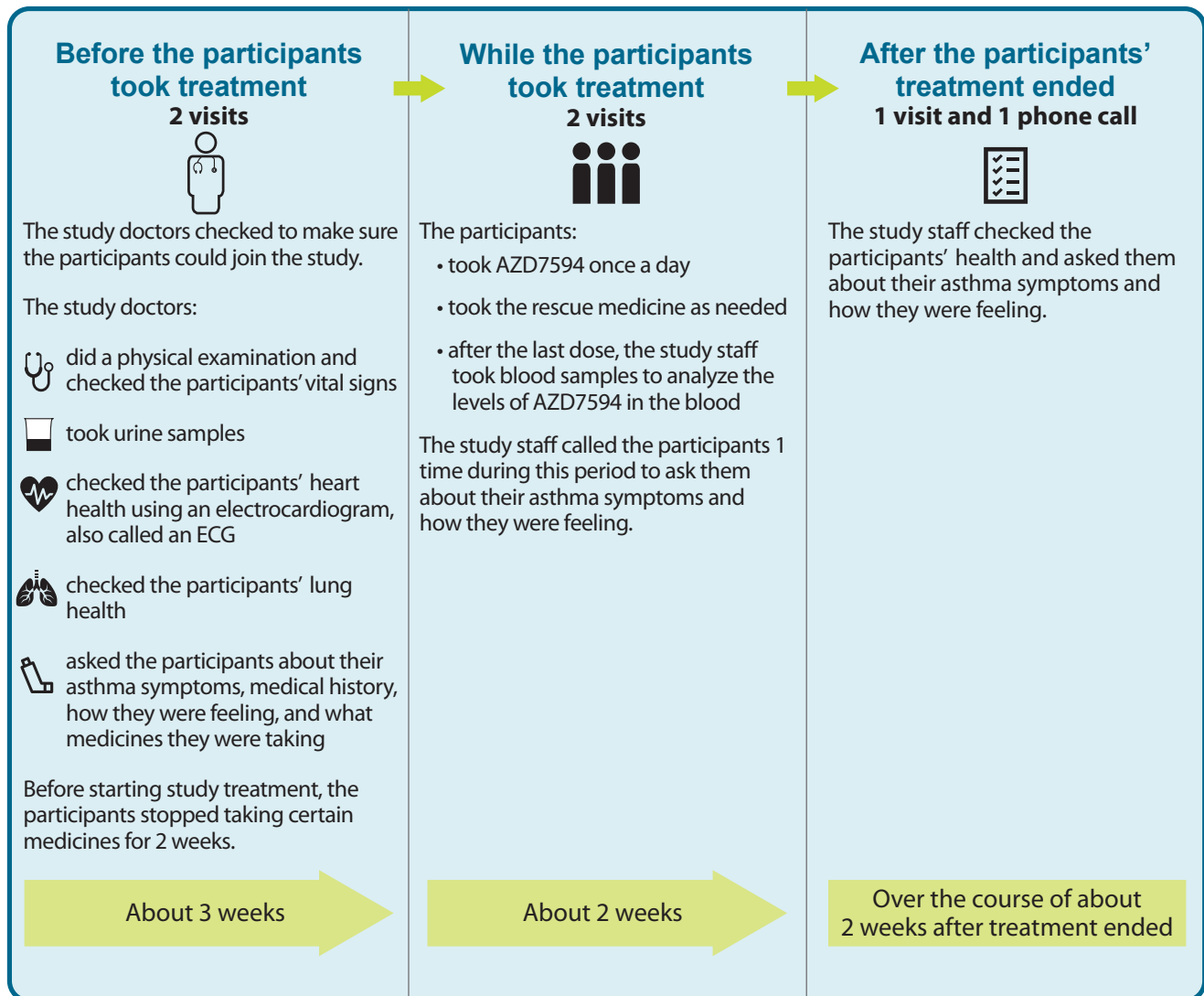
	Participants 12 to 14 years old (20 participants)	Participants 15 to 17 years old (16 participants)
	<ul style="list-style-type: none">• 360 µg of AZD7594	<ul style="list-style-type: none">• 360 µg of AZD7594
	<ul style="list-style-type: none">• Through an inhaler	<ul style="list-style-type: none">• Through an inhaler
	<ul style="list-style-type: none">• Once a day for about 2 weeks	<ul style="list-style-type: none">• Once a day for about 2 weeks



What happened during the study?

The study started in July 2019 and ended in September 2020.

The chart below shows what happened during the study.





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 changes.

The websites listed at the end of this summary may have more information about the study results.

How did AZD7594 act in the blood?

To answer this question, the researchers took blood samples and measured the levels of AZD7594 in the participants' blood after the last dose was taken.

Within both groups, the researchers found that there were some differences in the levels of AZD7594 among the participants. The age of the participants did not seem to affect these levels.



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 drug. 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 drug. A lot of research is needed to know whether a drug causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the study drug.

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?

None of the participants had adverse reactions during this study that the study doctors thought were related to the study drug.

None of the participants had serious adverse reactions during this study that the study doctors thought were related to the study drug.



How has this study helped patients and researchers?

This study helped researchers learn how AZD7594 acted in the blood of adolescent participants with asthma.

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 not currently 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 **"NCT03976869"** into the search box and click **"Search"**.
- > www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D3741C00012"** into the search box, and click **"Find a Study"**.
- > www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2019-001259-37"** in the search box and click **"Search"**.

Full Study Title: An Open-Label, Multi-Centre, Phase I Study to Assess the Pharmacokinetics, Pharmacodynamics and Safety of 2-Week Treatment with Inhaled AZD7594 in Adolescents (12 to 17 years) with Asthma

AstraZeneca AB Protocol Number: D3741C00012

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 and their families 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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