Clinical Study Results

Research Sponsor: AstraZeneca

Drug Studied: AZD7594

Study Title: A study to learn if different doses of AZD7594 helped with breathing and controlling symptoms in participants with asthma.

Thank you!

Thank you for taking part in the clinical study for the study drug AZD7594.

You and all of the participants helped researchers learn more about AZD7594 to help people who have asthma.

AstraZeneca sponsored this study and believes it is important to share the results of the study with you and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you. We hope it helps you understand and feel proud of your important role in medical research.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

Overview

Why was the research needed?

Researchers are looking for a better way to treat asthma. Before a drug can be approved for participants to take, researchers do clinical studies to find out how it works and how safe it is.

What treatments did the participants take?

The participants in this study took AZD7594, a placebo, or an asthma treatment called fluticasone furoate. A placebo looks like a drug but does not have any medicine in it.

What were the results of the study?

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

- **Did different doses of AZD7594 affect the amount of air the participants could breathe out?**
  The researchers found that at some doses, the participants who took AZD7594 breathed out more air after 12 weeks. The participants who took the placebo also breathed out more air after 12 weeks.
- **Did the participants feel that AZD7594 helped them control their asthma?**
  Yes. Overall, the researchers found that the participants who took AZD7594 felt that it helped them control their asthma compared to the participants who took the placebo.
- **What medical problems did the participants have during the study?**
  There were 2.5% of participants who had medical problems that the study doctors thought might be related to the study drug during the study. The most common medical problems were a cough and loss of voice. More details about the results of this study are included later in this summary.
- **Where can I learn more about this study?**
  You can find out more information about this study on the websites listed on the last page. When a full report of the study results is available, it can also be found on those websites.

Who took part in the study?

The researchers asked for the help of men and women with asthma. The participants in this study were 18 to 83 years old when they joined. The participants were already taking a steady dose of asthma treatment including inhaled corticosteroid, also called ICS. But, they were still having asthma symptoms.

The study included 806 participants in Bulgaria, Germany, Hungary, Japan, Poland, South Africa, Ukraine, and the United States.

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 it works and how safe it is.

Asthma is a condition that causes the airways to narrow. This makes it difficult to breathe. People with asthma may wheeze, cough, and have shortness of breath and chest tightness. There are treatments that can help control asthma symptoms, but these may not fully control asthma for some people.

Asthma treatments are usually taken through an inhaler. The study drug, AZD7594, is an inhaled treatment and works by reducing inflammation in the breathing tubes to allow more air into the lungs. Researchers think this will make it easier for people with asthma to breathe.

In this study, the researchers wanted to find out if AZD7594 works in participants with asthma. They also wanted to find out if the participants had any medical problems during the study.

What was the purpose of this study?

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

- Did different doses of AZD7594 affect the amount of air the participants could breathe out?
- Did the participants feel that AZD7594 helped them control their asthma?
- 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 to find out if AZD7594 helps improve breathing and symptoms in people with asthma.

What treatments did the participants take?

Before the participants took any study treatment, they took an ICS asthma treatment called budesonide twice daily for up to 4 weeks. Then, a computer program was used to randomly choose the treatment each participant took. 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.

There were 2 parts to this study that happened at the same time. There was 1 part that was “double-blind”. This means none of the participants, researchers, study doctors, or other study staff knew what treatment each participant was taking.

In the double-blind part, the participants took either AZD7594 or a placebo through an inhaler. A placebo looks like a 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 the drug are actually caused by the drug.

The doses of AZD7594 were measured in micrograms, also known as µg. The participants took 1 puff of their inhaler once a day. There were 6 different treatment groups in this part. The table below shows the treatments that were planned in the double-blind part.

There was also an “open-label” part of the study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking. In this part of the study, 112 participants took an ICS asthma treatment called fluticasone furoate, also called FF. The participants took 1 puff of their FF inhaler once a day.

The table below shows the treatments that were planned in the study.

Group	Treatment
Group 1 (111 participants)	50 µg of AZD7594
Group 2 (112 participants)	90 µg of AZD7594
Group 3 (111 participants)	180 µg of AZD7594
Group 4 (113 participants)	360 µg of AZD7594
Group 5 (134 participants)	720 µg of AZD7594
Group 6 (113 participants)	Placebo
Group 7 (112 participants)	100 µg of FF

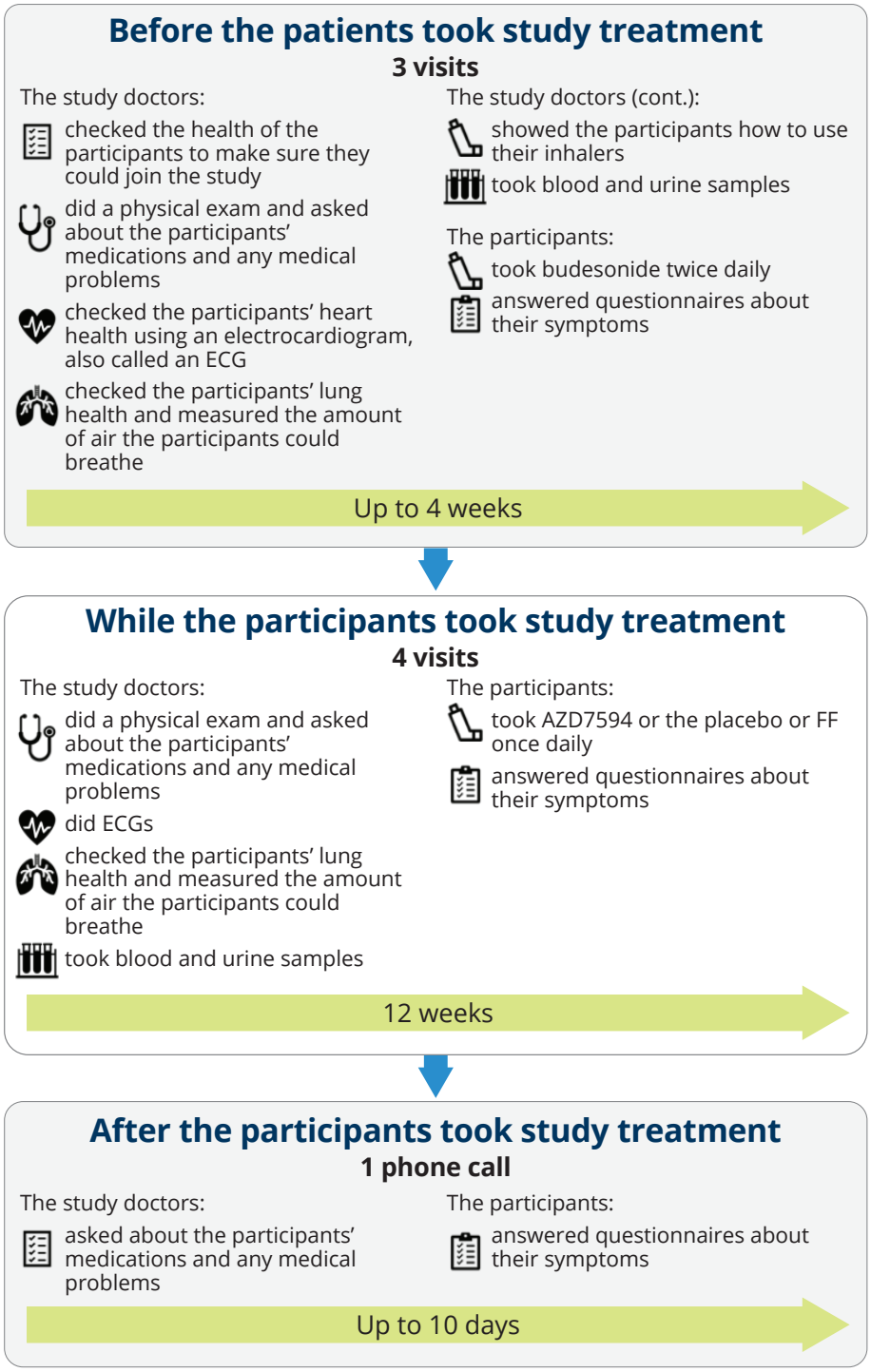
If the participants had asthma symptoms at any time during the study, they could also take an asthma treatment called salbutamol/albuterol, also called SABA.

What happened during the study?

The participants were in the study for about 4 months. But, the entire study took 9 months to finish.

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

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. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When a full report of the study results is available, it can also be found on these websites.

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.

There was 1 participant who left the study before taking any treatment. So, the results below include information for 805 out of 806 participants.

Did different doses of AZD7594 affect the amount of air the participants could breathe out?

To answer this question, the study doctors measured the amount of air the participants breathed out in 1 second. This was measured in milliliters, also called mL. The study doctors compared the average amount breathed out after 12 weeks of treatment to the average amount breathed out before the participants started taking treatment.

The researchers found that in each treatment group, there was a change in the amount of air that the participants breathed out after 12 weeks of treatment. At some doses, the participants who took AZD7594 breathed out more air after 12 weeks. The participants who took the placebo and FF also breathed out more air after 12 weeks. But, the differences between treatment groups were too small for the researchers to know if AZD7594 affected the participants' breathing compared to the placebo.

The table below shows the results for each treatment group after 12 weeks of taking study treatment.

Group	Average change in air breathed out
Group 1 50 µg of AZD7594	13 mL **less** air
Group 2 90 µg of AZD7594	31 mL **less** air
Group 3 180 µg of AZD7594	62 mL **more** air
Group 4 360 µg of AZD7594	99 mL **more** air
Group 5 720 µg of AZD7594	104 mL **more** air
Group 6 Placebo	22 mL **more** air
Group 7 100 µg of FF	133 mL **more** air

Did the participants feel that AZD7594 helped them control their asthma?

Yes. Overall, the researchers found that the participants who took AZD7594 felt that it helped them control their asthma compared to the participants who took the placebo.

To answer this question, the study doctors asked the participants to answer a questionnaire about their asthma symptoms. The questionnaire is called the Asthma Control Questionnaire-5, also called ACQ-5. The participants received scores from 0 to 5 based on their responses. A higher score on the ACQ-5 means asthma symptoms are less controlled. The researchers compared the average score after 12 weeks of treatment to the average score before the participants started taking treatment.

The table below shows the how much the participants' ACQ-5 scores decreased for each treatment group after 12 weeks of taking study treatment.

Group	Average decrease in ACQ-5 score
Group 1 50 µg of AZD7594	0.3 points
Group 2 90 µg of AZD7594	0.4 points
Group 3 180 µg of AZD7594	0.4 points
Group 4 360 µg of AZD7594	0.3 points
Group 5 720 µg of AZD7594	0.4 points
Group 6 Placebo	0.1 points
Group 7 100 µg of FF	0.4 points

What medical problems did 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 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?

Groups 1 through 3

	Total (out of 805 participants)	50 µg of AZD7594 (out of 110 participants)	90 µg of AZD7594 (out of 112 participants)	180 µg of AZD7594 (out of 111 participants)
How many participants had adverse reactions?	2.5% (20)	2.7% (3)	2.7% (3)	2.7% (3)
How many participants left the study due to adverse reactions?	0.4% (3)	0.0% (0)	0.0% (0)	0.9% (1)

Groups 4 through 7

	360 µg of AZD7594 (out of 113 participants)	720 µg of AZD7594 (out of 134 participants)	Placebo (out of 113 participants)	100 µg of FF (out of 112 participants)
How many participants had adverse reactions?	4.4% (5)	2.2% (3)	1.8% (2)	0.9% (1)
How many participants left the study due to adverse reactions?	0.9% (1)	0.0% (0)	0.9% (1)	0.0% (0)

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

What adverse reactions happened during this study?

The most common adverse reactions were a cough and loss of voice.

The adverse reactions below happened in 2 or more participants. There were other adverse reactions, but these happened in fewer participants.

Most common adverse reactions
Groups 1 through 3

Adverse reaction	Total (out of 805 participants)	50 µg of AZD7594 (out of 110 participants)	90 µg of AZD7594 (out of 112 participants)	180 µg of AZD7594 (out of 111 participants)
Cough	0.5% (4)	1.8% (2)	0.0% (0)	0.0% (0)
Loss of voice	0.5% (4)	0.0% (0)	0.9% (1)	0.0% (0)
Anxiety	0.2% (2)	0.0% (0)	0.0% (0)	0.9% (1)
Headache	0.2% (2)	0.0% (0)	0.0% (0)	0.9% (1)

Most common adverse reactions
Groups 4 through 7

Adverse reaction	360 µg of AZD7594 (out of 113 participants)	720 µg of AZD7594 (out of 134 participants)	Placebo (out of 113 participants)	100 µg of FF (out of 112 participants)
Cough	0.9% (1)	0.7% (1)	0.0% (0)	0.0% (0)
Loss of voice	1.8% (2)	0.0% (0)	0.9% (1)	0.0% (0)
Anxiety	0.9% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Headache	0.9% (1)	0.0% (0)	0.0% (0)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about AZD7594 in 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 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 **"NCT03622112"** into the search box, and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click "Home and Search", then type **"2017-002483-40"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D3741C00007"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase 2b Randomised, Double-Blind, Placebo-Controlled, Parallel Arm, Multi-Centre Study to Assess Efficacy and Safety of Multiple Dose Levels of AZD7594 DPI Given Once Daily for Twelve Weeks, Compared to Placebo, in Asthmatics Symptomatic on Low Dose ICS.

AstraZeneca Protocol Number: D3741C00007

National Clinical Trials Number: NCT03622112

EudraCT Number: 2017-002483-40

AstraZeneca sponsored this study and has its headquarters in Cambridge, UK.

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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