

Clinical Trial Results



Research Sponsor: AstraZeneca AB
Drugs Studied: AZD7594 and Abediterol
National Clinical Trial #: NCT02967159
Eudra Clinical Trial #: 2016-002533-30
Protocol #: D7110C00001
Study Date: November 2016 to April 2017
Short Study Title: A study in healthy participants to compare how AZD7594 and abediterol act in the body when taken alone and together through an inhaler

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for the drugs AZD7594 and abediterol. These drugs are being developed to treat asthma and chronic obstructive pulmonary disease, also called COPD. You and all of the participants helped researchers learn how AZD7594 and abediterol act in the body and if these drugs cause medical problems.

AstraZeneca AB, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the study doctor or staff at your study site.

What's happened since my study ended?

Your study started in November 2016 and ended in April 2017. The study included 32 participants at 1 study site in Germany. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Before a new drug can be given to patients, the company developing it must do research studies to show that the drug is safe and effective. The first step in studying a new drug is to test it in healthy people. This means people without any serious health problems.

The study drug, AZD7594, is being developed to treat asthma and COPD. These illnesses can cause inflammation, or swelling in tissues, in the lungs. This swelling can sometimes make breathing difficult. Inhalers that contain steroids are used in patients with COPD and asthma to reduce inflammation. AZD7594 does not contain steroids, but it works in a similar way to steroids taken by an inhaler.

In this study, researchers compared taking AZD7594 alone and together with another drug called abediterol. AZD7594 works by relaxing and expanding your airways after being inhaled. Both study drugs were in the form of a dry powder inhaler, also called DPI. The study drugs were put into a sealed chamber inside the inhaler. A dose of the study drug was released every time you pressed the inhaler and breathed in. Researchers wanted to see how much of the study drugs entered the blood of each participant after using the inhalers.

Researchers wanted to know:

- How did AZD7594 and abediterol act in the body when they were taken alone and taken together?
- What medical problems did participants have after taking the study drugs?

What kind of study was this?

Your study was an “open-label” study. This means that the participants and study staff knew what study drug each participant took.

Your study was also a “crossover” study. In a crossover study, all participants get the same treatments and tests, but the treatments are given in a random order, like rolling dice. In this study, all participants took AZD7594 and abediterol, but in a different order.

Your study included healthy men who were 21 to 55 years old.

What happened during the study?

You and other participants were in the study for about 16 weeks.

To see if you could join the study, study doctors did a physical examination by checking your height, weight, blood pressure, pulse, and temperature. Study doctors also took blood and urine samples, checked your lung health, and checked your heart health using an electrocardiogram, or ECG. Study doctors also asked about your medical history, how you were feeling, and what medicines you were taking.

During the study, there were 4 different treatment periods of 11 days each. During each treatment period, participants stayed at the study site for 3 days. During this time, each participant took the following treatments through inhalers, but in different orders:

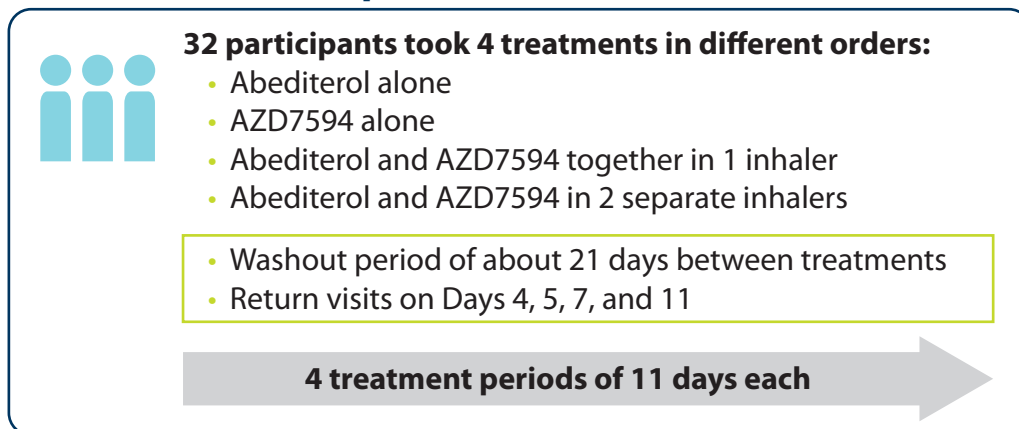
- 2.5 µg, or micrograms, of abediterol
- 440 µg of AZD7594
- 2.5 µg of abediterol and 440 µg of AZD7594 together in 1 inhaler
- 2.5 µg of abediterol and 440 µg of AZD7594 in 2 separate inhalers

There was a “washout period” of about 21 days between each treatment. This means that when participants take the next study treatment, all drugs have been processed and “washed out of their bodies. During the washout period, you were not allowed to take certain drugs.

During the study, participants returned to the study site on Days 4, 5, 7, and 11 of each treatment period. During these visits, researchers did blood and urine tests, physical examinations, and other tests to check your overall health. Researchers checked your heart health using an ECG and checked your lung health. Researchers also asked you how you were feeling and if you were taking any other medicines.

The figure below shows how the study was done.

Open-label treatment



Participants had a final visit about 10 to 14 days after getting the last treatment. During this visit, researchers did a physical examination, took blood and urine samples, and checked your heart health using an ECG. Researchers also checked your blood pressure, heart rate, and temperature and asked you how you were feeling and what medicines you were taking.

What were the study results?

Below is a summary of the results of some of the questions the researchers asked during the study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with AZD7594 and abediterol are planned.

How did AZD7594 and abediterol act in the body when they were taken alone and taken together?

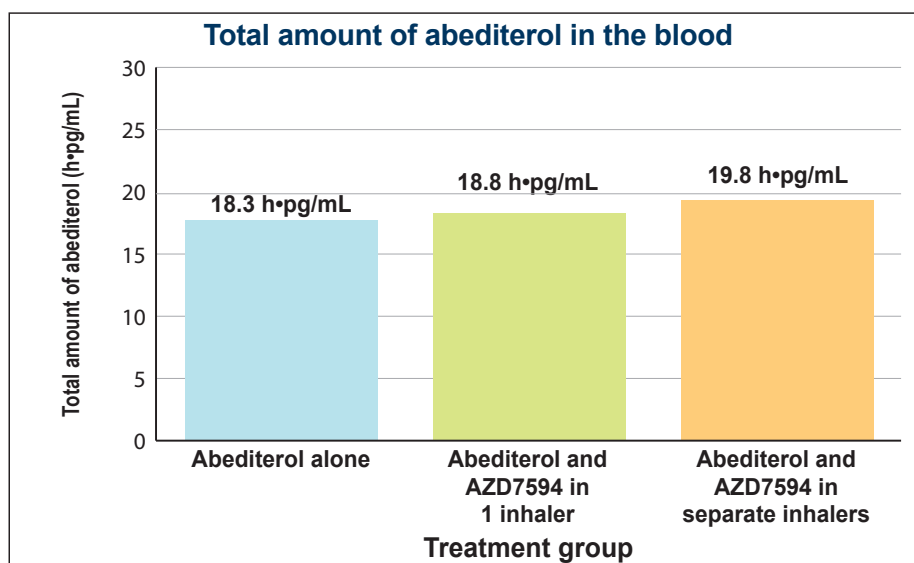
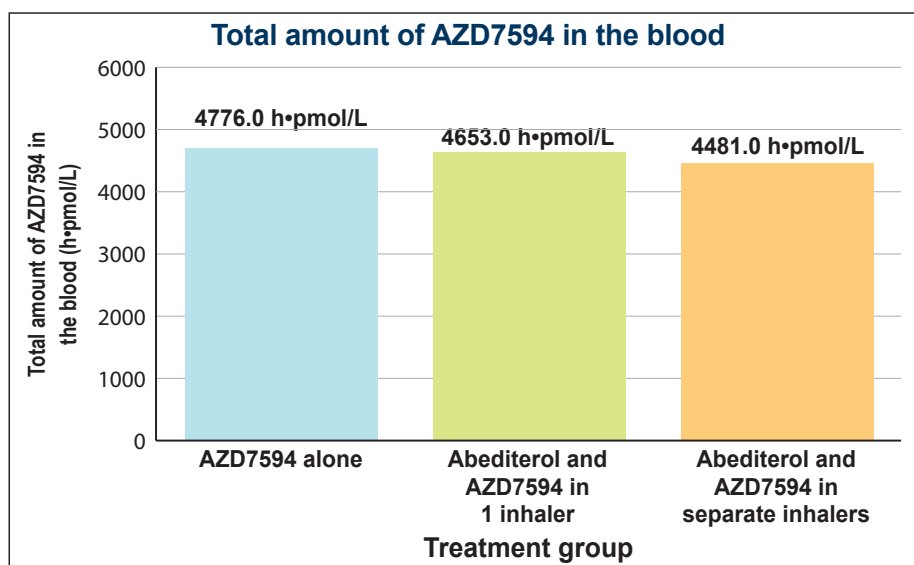
Researchers looked at how AZD7594 and abediterol acted in the body when participants took the drugs alone and together. Researchers looked at the following:

- The total amount of the study drugs in the blood
- The highest amount of the study drugs in the blood
- The time it took for the study drugs to reach their highest amounts in the blood

Overall, researchers found that participants had about the same total and highest amounts of AZD7594 and abediterol in their blood, whether they took the study drugs alone or together. Both study drugs took about the same length of time to reach their highest amounts in the blood of participants.

Total amount of the study drugs in the blood

Researchers measured the total amount of AZD7594 in picomole hours per liter of blood, or h•pmol/L. Researchers measured the total amount of abediterol in picogram hours per milliliter of blood, or h•pg/mL. These are widely accepted scientific units of measurement. The charts below show the total amounts of the study drugs that participants had in their blood.

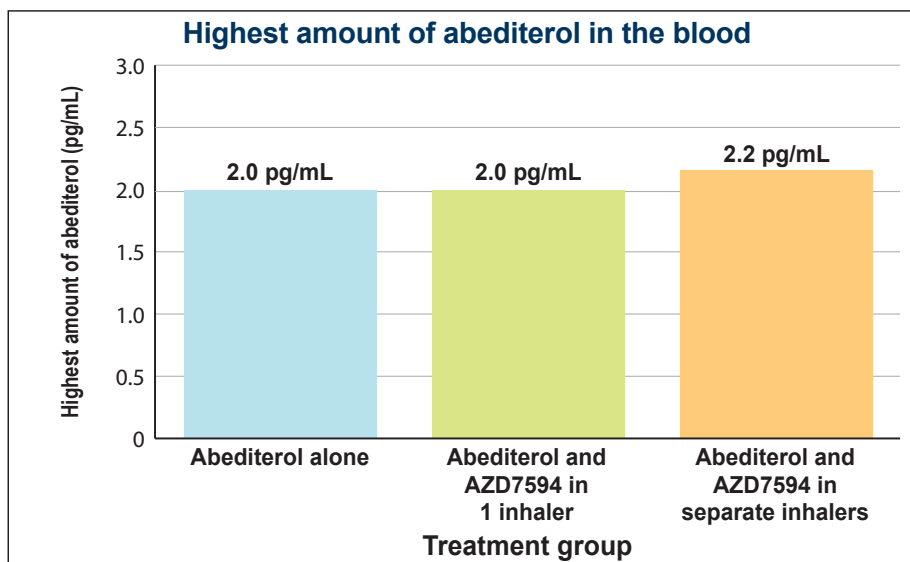
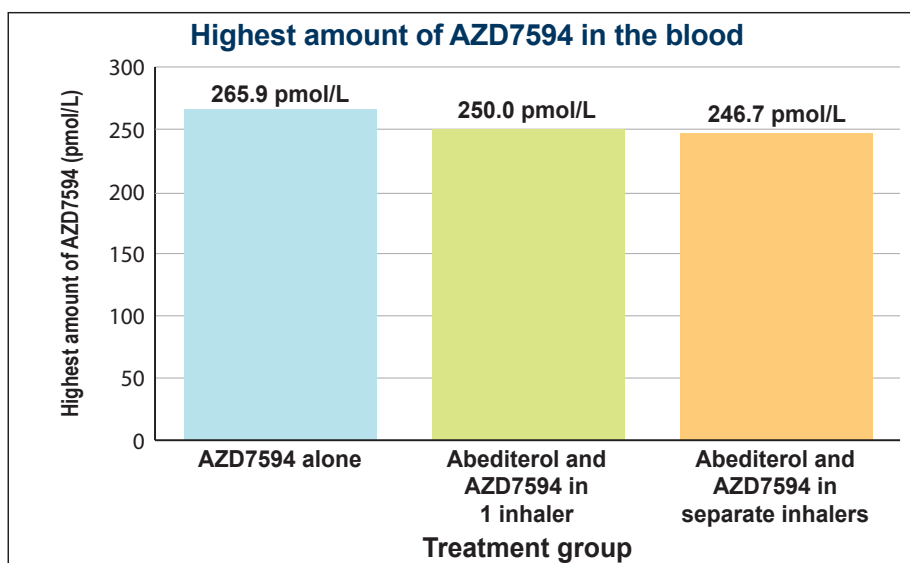


Highest amount of the study drugs in the blood

Researchers measured the highest amount of AZD7594 in picomoles per liter of blood, or pmol/L.

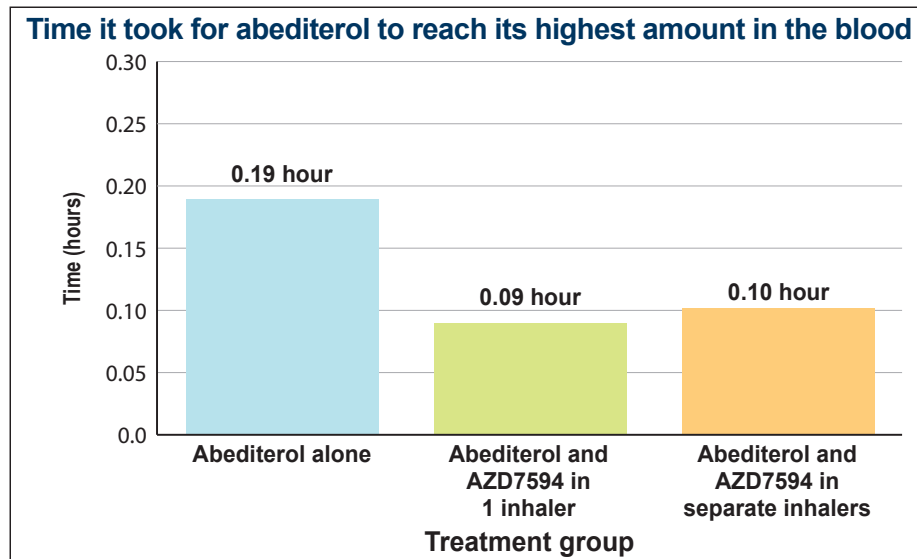
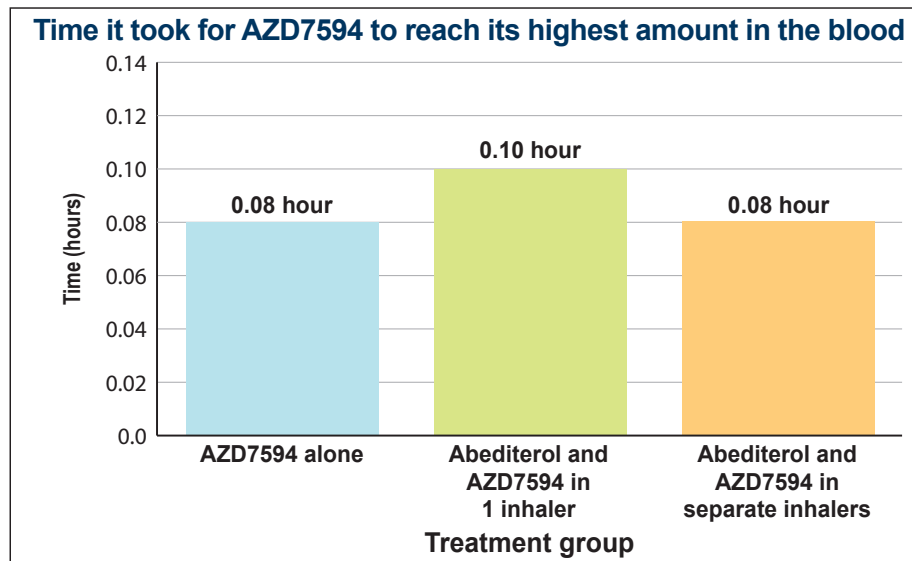
Researchers measured the highest amount of abediterol in picograms per milliliter of blood, or pg/mL.

These are widely accepted scientific units of measurement. The charts below show the highest amounts of the study drugs that participants had in their blood.



Time it took for the study drugs to reach their highest amounts in the blood

Researchers measured the time it took for the study drugs to reach their highest amounts in the blood. The charts below show this time.



What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are being studied, researchers keep track of all medical problems that participants have during the study. These medical problems are called “adverse events”. They may or may not be caused by the study drug.

How many participants had medical problems during the study?

About the same number of participants had medical problems after taking abediterol or AZD7594 alone and after taking the study drugs in separate inhalers. Fewer participants had medical problems after taking abediterol and AZD7594 together in 1 inhaler. Two participants (6.3%) stopped taking the study drugs because of medical problems. Study doctors felt these medical problems were not related to AZD7594 or abediterol.

The table below shows how many participants had medical problems in this study.

Medical problems in this study				
	Abediterol alone (out of 30 participants)	AZD7594 alone (out of 31 participants)	Abediterol and AZD7594 together in 1 inhaler (out of 30 participants)	Abediterol and AZD7594 in separate inhalers (out of 31 participants)
How many participants had medical problems?	8 (26.7%)	9 (29.0%)	5 (16.7%)	9 (29.0%)
How many participants had serious medical problems?	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)
How many participants stopped taking the study drugs because of medical problems?	0 (0.0%)	1 (3.2%)	0 (0.0%)	1 (3.2%)

How many participants had serious medical problems?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospital care. In this study, no participants died and 1 out of the 31 participants (3.2%) had a serious medical problem. Study doctors felt that the serious medical problem was not related to AD7594 or abediterol.

What were the most common non-serious medical problems in the study?

The table below show the most common medical problems that happened in at least 5% of participants in any treatment group during the study.

Most common non-serious medical problems in this study				
	Abediterol alone (out of 30 participants)	AZD7594 alone (out of 31 participants)	Abediterol and AZD7594 together in 1 inhaler (out of 30 participants)	Abediterol and AZD7594 in separate inhalers (out of 31 participants)
Headache	5 (16.7%)	2 (6.5%)	1 (3.3%)	4 (12.9%)
Common cold	3 (10.0%)	1 (3.2%)	0 (0.0%)	3 (9.7%)
Stuffy nose	0 (0.0%)	0 (0.0%)	2 (6.7%)	0 (0.0%)
Diarrhea	2 (6.7%)	1 (3.2%)	0 (0.0%)	0 (0.0%)

Where can I learn more about the study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02967159.

Official study title: A Randomized, Open-Label Cross-Over Study To Evaluate Pharmacokinetics And Safety Of Single Inhaled Doses Of Abediterol And AZD7594 Given Alone, In Fixed Dose Combination (FDC) And In Free Combination, Using Dry Powder Inhaler (DPI) In Male Healthy Volunteers

AstraZeneca AB is the sponsor of this study and has its headquarters in Södertälje, Sweden.

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

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical study. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.



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 trials, nor is it involved in conducting clinical studies.

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