Clinical Trial Results

AstraZeneca

Research Sponsor:	AstraZeneca AB
Drugs Studied:	AZD7594
National Clinical Trial #:	NCT02928354
Eudra CT #:	2016-003397-41
Protocol #:	D3741C00006
Study Date:	November 2016 to March 2017
Short Study Title:	A study in healthy male volunteers to learn how different inhaler treatments of AZD7594 act in the body

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 this clinical study for the drug AZD7594. This drug is being developed to treat chronic obstructive pulmonary disease, also known as COPD, and asthma. You and all of the other participants helped researchers learn how different inhaled forms of AZD7594 act in the body and if AZD7594 causes any 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 doctors or staff at your study site.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

What's happened since my study ended?

Your study started in November 2016 and ended in March 2017. It included 18 male 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 it is safe and effective. The first step in studying a new drug is to test it in healthy people, or people without any serious health problems.

The study drug, AZD7594, is being developed to treat COPD and asthma. 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 3 inhaler treatments that deliver AZD7594 in powder form. A dose of the study drug was released every time you pressed the inhaler and breathed in. The same dose of the study drug was used for all 3 treatments. Although the 3 doses were the same, each powder was made up of a different sized particle. A particle is 1 piece, or granule, of AZD7594 in the powder.

Researchers wanted to know:

- How did AZD7594 act in the body when participants took it in different particle sizes?
- What medical problems did participants have after they took AZD7594?

What kind of study was this?

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

The study was also a "crossover" study. This means that all participants took the same treatments but in a random order.

Your study included 18 healthy men who were 25 to 54 years old.

What happened during the study?

You and other participants were in the study for up to about 15 weeks.

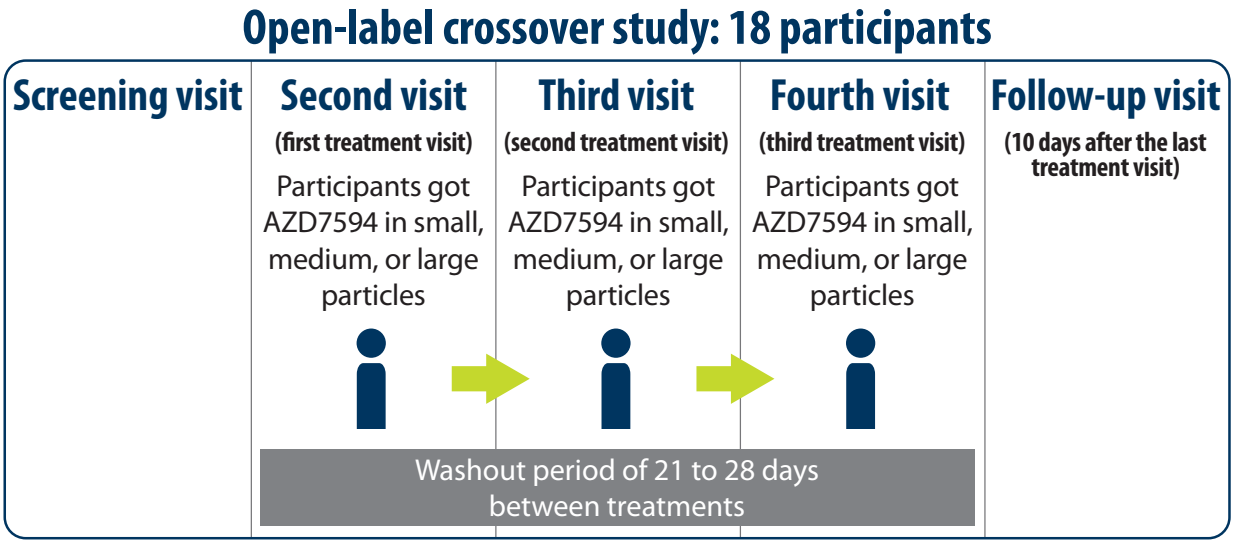
To see if you could join the study, study doctors did a physical examination by checking your height, weight, and temperature. Study doctors took blood samples and checked your heart health using an electrocardiogram, or ECG. Study doctors also asked about your medical history, how you were feeling,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

In this study, participants took small, medium, and large particle sizes of AZD7594 through an inhaler. Participants took all 3 treatments but in a random order.

During the study, you visited a study site 5 times. Study doctors did more physical examinations, including checking your height, weight, and heart health. Study doctors asked again about how you were feeling and what medicines you were taking.

There was a "washout period" of 21 to 28 days between taking each of the 3 treatments. During the washout periods, participants did not take any drugs. This helped get rid of any effects from previous treatments.

The figure below shows how the study was done.



During the follow-up visit, study doctors did another physical examination, including checking your height, weight, and heart health. Study doctors asked again about your 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 this 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 are planned.

The results below are for 16 out of the original 18 participants. This is because 2 participants left the study before it was completed.

How did AZD7594 act in the body when participants took it in different particle sizes?

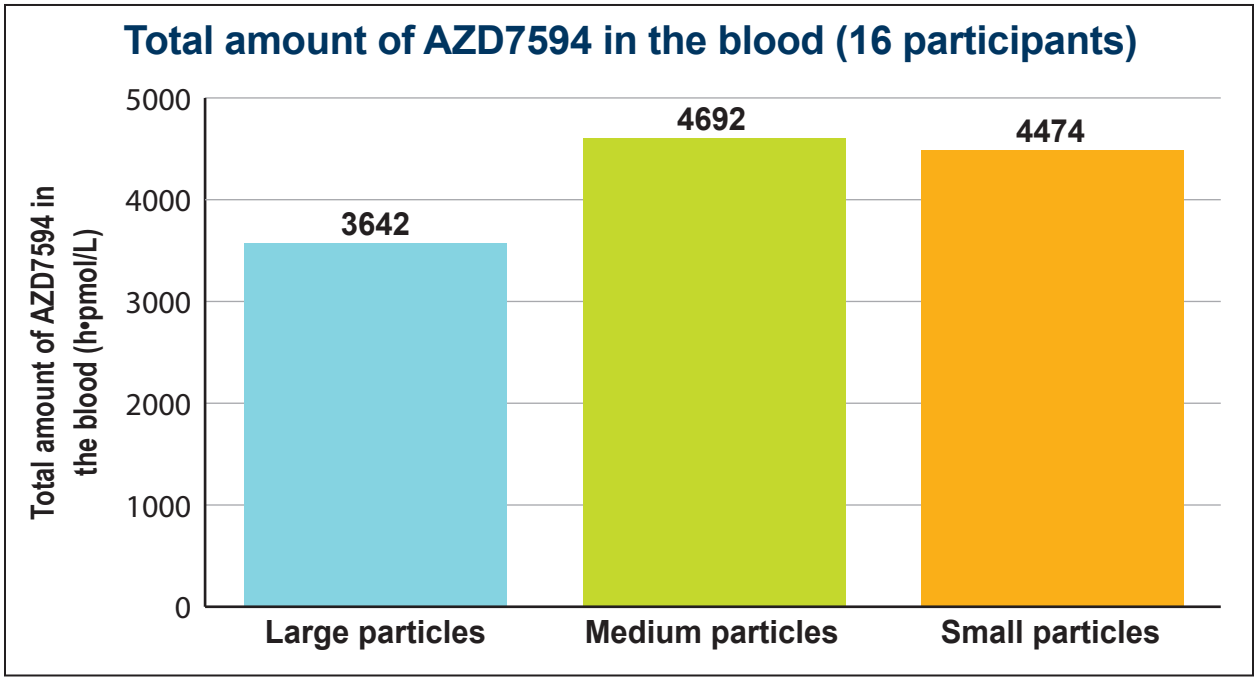
Researchers wanted to know how AZD7594 acts in the body when given in different particle sizes. They wanted to know:

- The total amount of AZD7594 in the blood
- The highest amount of AZD7594 in the blood
- How long it took for AZD7594 to reach its highest amount in the blood

Total amount of AZD7594 in the blood

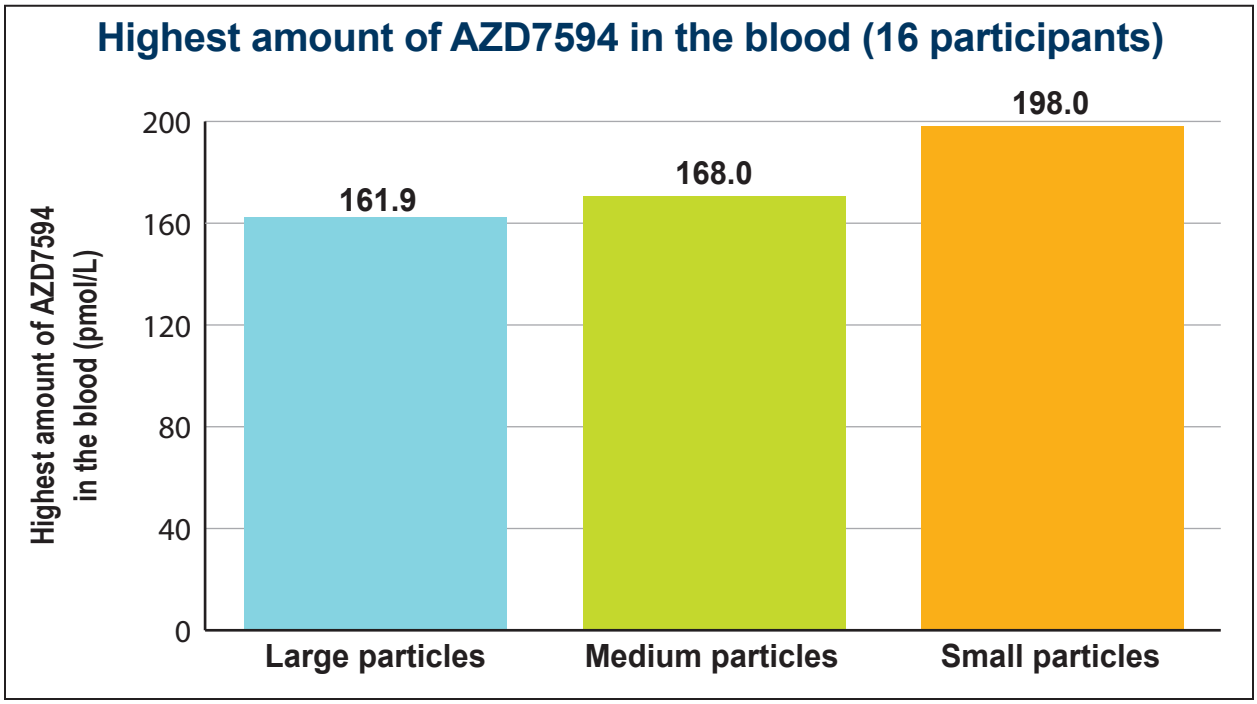
Researchers measured the total amount of AZD7594 in participants' blood in picomole hours per liter of blood (h•pmol/L).

The figure below shows this amount for the 3 AZD7594 treatments.



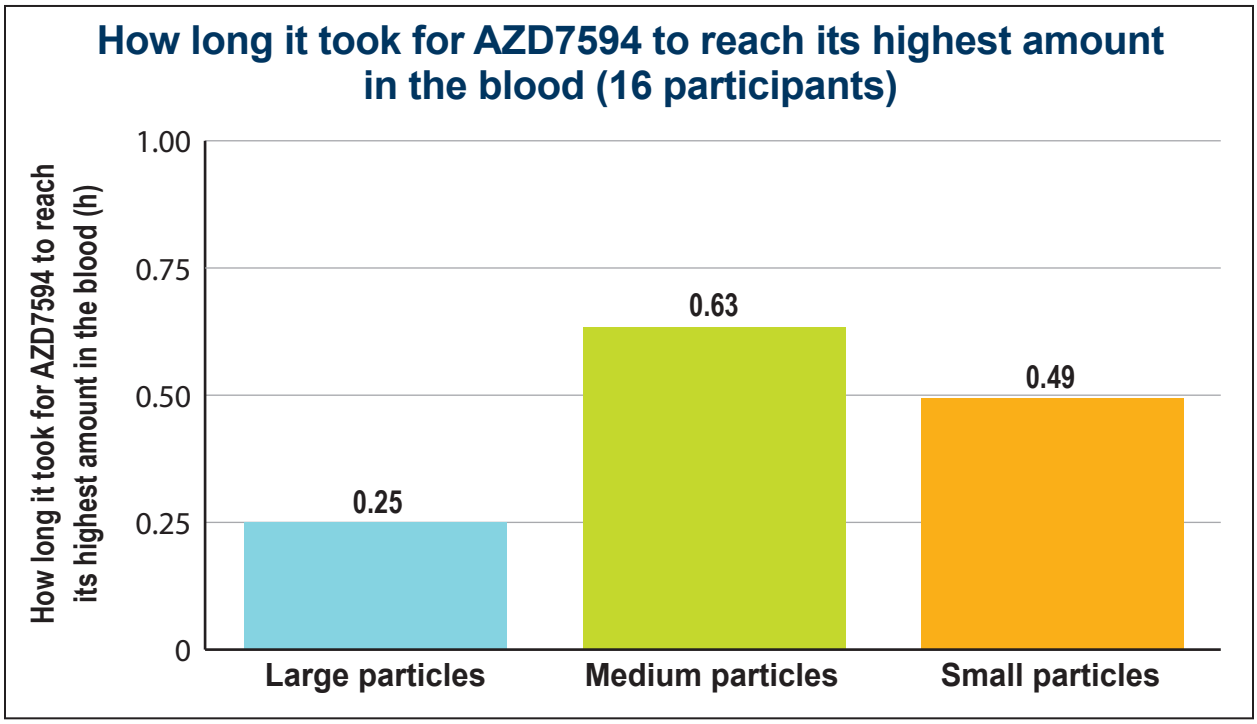
Highest amount of AZD7594 in the blood

Researchers measured the highest amount of AZD7594 in participants' blood in picomoles per liter of blood (pmol/L). The figure below shows this amount for the 3 AZD7594 treatments.



How long it took for AZD7594 to reach its highest amount in the blood

Researchers measured how long it took in hours (h) for AZD7594 to reach its highest amount in the blood. The figure below shows this amount of time for the 3 AZD7594 treatments.



Overall, researchers found:

- Participants had a higher total amount of AZD7594 in their blood when they took the small- and medium-sized particle treatments compared to the large-sized particle treatment. The small- and medium-sized particle treatment had similar total amounts to each other.
- Participants had the highest amount of AZD7594 in their blood when they took the small-sized particle treatment. The highest amount was similar with the medium- and large-sized particle treatments.
- It took an average of 25 to 49 minutes for AZD7594 to reach its highest amount in the blood.

What medical problems did participants have after they took AZD7594?

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 developed medical problems in the study?

The table below shows how many participants in each treatment group developed medical problems.

	AZD7594 large particles (Out of 18 participants)	AZD7594 medium particles (Out of 18 participants)	AZD7594 small particles (Out of 18 participants)
How many participants developed medical problems?	3 (16.7%)	6 (33.3%)	5 (27.8%)

How many participants developed serious medical problems?

A medical problem is considered serious when it is life-threatening, causes lasting problems, or needs hospitalization. No participants developed serious medical problems during this study. No participants died during this study.

What were the medical problems in the study that were not considered serious?

The table below shows all non-serious medical problems that happened in any participant in each treatment group in the study.

	AZD7594 large particles (Out of 18 participants)	AZD7594 medium particles (Out of 18 participants)	AZD7594 small particles (Out of 18 participants)
Hay fever	1 (5.6%)	1 (5.6%)	1 (5.6%)
Blood clot in vein	1 (5.6%)	0 (0.0%)	1 (5.6%)
Headache	1 (5.6%)	0 (0.0%)	1 (5.6%)
Common cold	0 (0.0%)	2 (11.1%)	2 (11.1%)
Irritated skin	0 (0.0%)	2 (11.1%)	1 (5.6%)
Discomfort in arms or legs	0 (0.0%)	1 (5.6%)	0 (0.0%)
Swollen, red eyelid	0 (0.0%)	0 (0.0%)	1 (5.6%)

Where can I learn more about the study?

If you have questions about the results, please speak with the study doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/results/NCT02928354.

Official study title: A Randomized Open Label Three-Way Crossover Study in Healthy Male Volunteers to Investigate the Effect of Particle Size on Pharmacokinetics Following a Single Inhaled Dose of AZD7594 Via a Dry Powder Inhaler

AstraZeneca AB, the sponsor of this study, has its headquarters at 1800 Concord Pike, Wilmington, DE 19850.

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.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

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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