Clinical Trial RESULTS

AstraZeneca

Research Sponsor:	AstraZeneca AB
Drugs Studied:	AZD7594
National Clinical Trial #:	NCT02645253
Protocol #:	D3741C00005
Study Date:	January 2016 to April 2016
Short Study Title:	A study to compare the effects of AZD7594 in healthy male participants

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 drug AZD7594. This drug is being developed to treat asthma and chronic obstructive pulmonary disease, or COPD. You and all of the participants helped researchers learn how AZD7594 acts in the body and if AZD7594 causes 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 doctor or staff at your study site.

What's happened since my study ended?

Your study started in January 2016 and ended in April 2016. It included 27 participants at 1 study site in the United States. 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 the drug 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 asthma and COPD. Asthma is a lung disease that causes chest wheezing and difficulty breathing. COPD is a lung disease that lessens the flow of air to the lungs.

Inhalers that contain steroids are used by patients with asthma and COPD to reduce inflammation, or the swelling that can occur in lung tissue. This swelling can sometimes make breathing difficult. AZD7594 does not contain steroids but it works in a similar way to inhalers that do contain steroids.

Researchers compared 3 different doses of AZD7594 to a placebo. A placebo looks like the study drug but contains no real medicine. The study drugs were taken through a dry powder inhaler, also called a DPI. Researchers wanted to know:

- How did AZD7594 act in the body?
- How was the body affected by AZD7594?
- What medical problems did participants have after they took AZD7594?

What kind of study was this?

Your study was "single-blind". In this study, this means that some study staff knew what study drug each participant took, but the participants did not. In this study, participants took either AZD7594 or a placebo.

Your study included healthy men who were 26 to 44 years old.

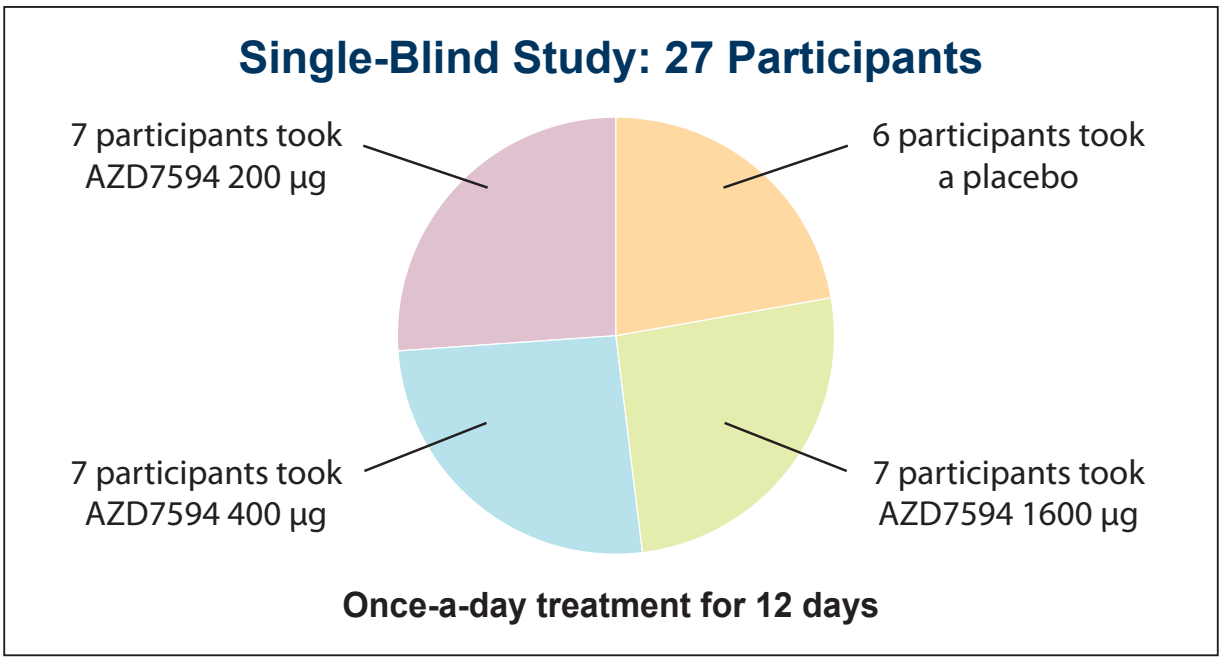
What happened during the study?

You and other participants were in the study for up to 59 days. Participants stayed at the study site for 2 days before receiving the study drug and for 20 days after receiving the study drug.

During the study, 27 participants were assigned to one of 3 treatment groups. Participants in each of the 3 groups had a 7 out of 9 chance of getting AZD7594 and a 2 out of 9 chance of getting the placebo. The 3 treatments are listed below:

- 200 micrograms (µg) AZD7594 (1 puff) or placebo
- 400 µg AZD7594 (1 puff) or placebo
- 1600 µg AZD7594 (4 puffs of a 400-µg inhaler) or placebo

Participants took the study drug once on Day 1 and then did not take the study drug on Days 2, 3, or 4. Starting on Day 5, participants took the study drug once a day until Day 16, which was a 12-day period. Researchers wanted there to be a few days in between treatments so that they could observe the effects of each dose and not the effects of multiple doses. The figure below shows how the study was done.



During the study, researchers did blood and urine tests and physical exams. They also trained participants on how to correctly use the inhalers. Researchers also checked your heart using an electrocardiogram (ECG). Participants had a final follow-up visit around 9 days after leaving the study center to make sure they were still healthy.

What were the study results?

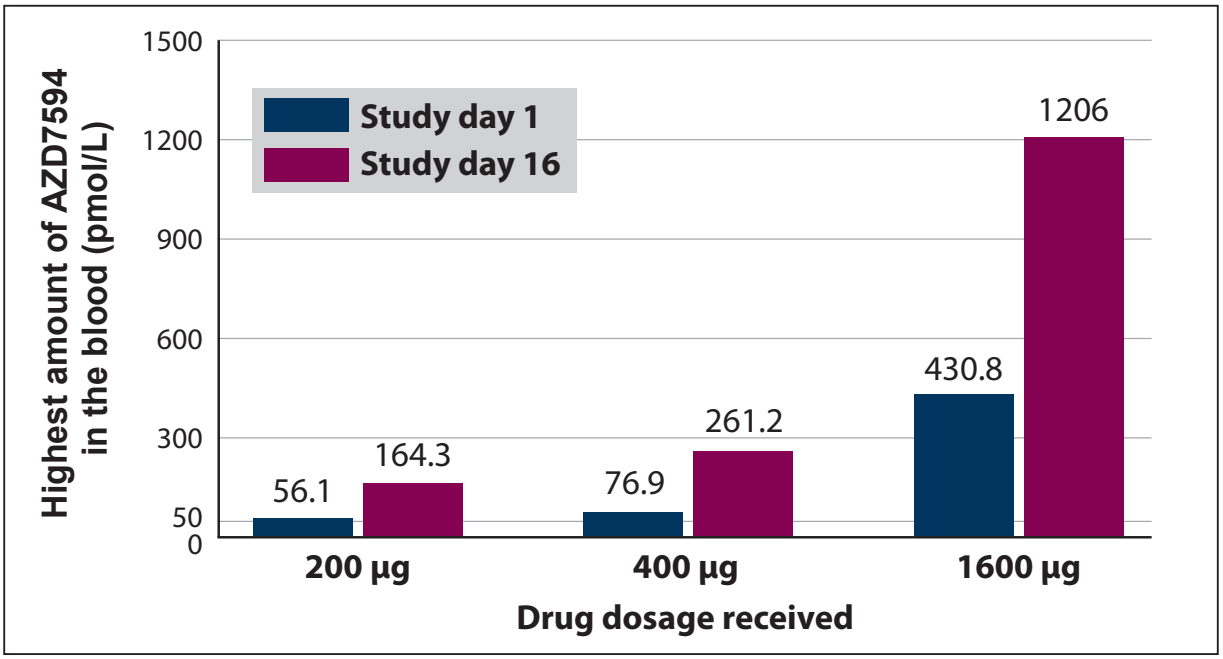
How did AZD7594 act in the body?

Researchers took blood samples both on Day 1 after the first dose of the study drug and on Day 16 after the last dose of the study drug. Participants took the study drug once on Day 1 and then did not take the study drug on Days 2, 3, or 4. Starting on Day 5, participants took the study drug once a day until Day 16, which was a 12-day period. Researchers wanted to see how the study drug acted in the body, including the following:

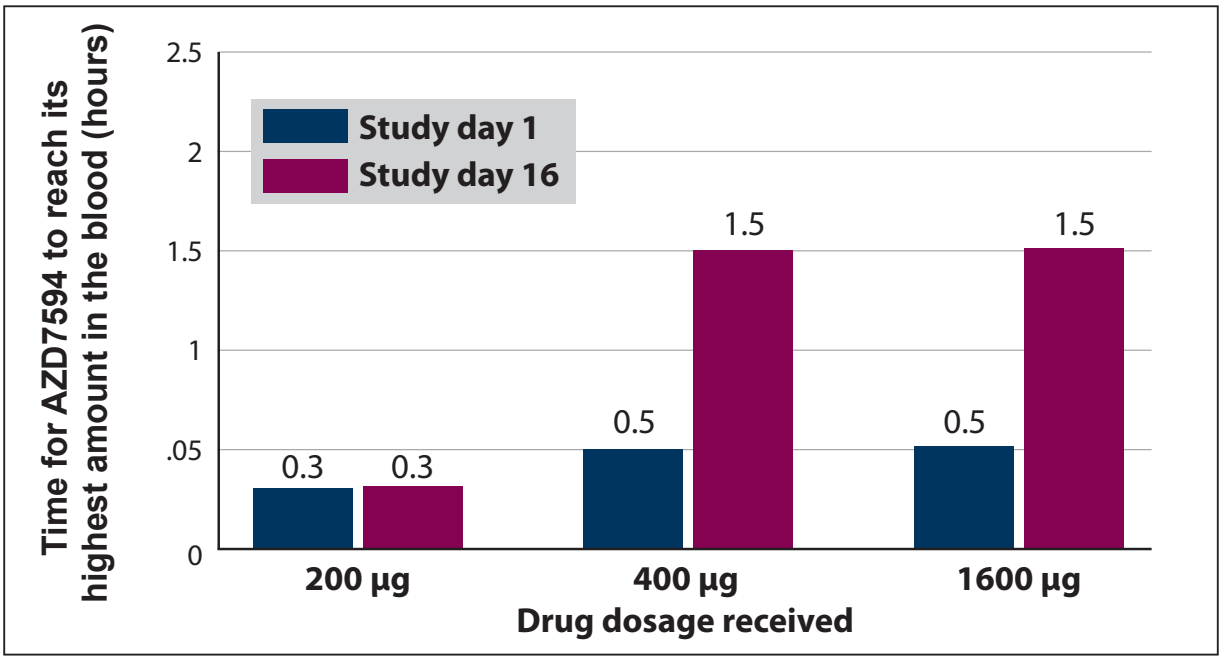
- The highest amount of AZD7594 in the blood
- How long it took for AZD7594 to reach its highest amount in the blood
- The overall daily amount of AZD7594 in the blood

Highest amount of AZD7594 in the blood

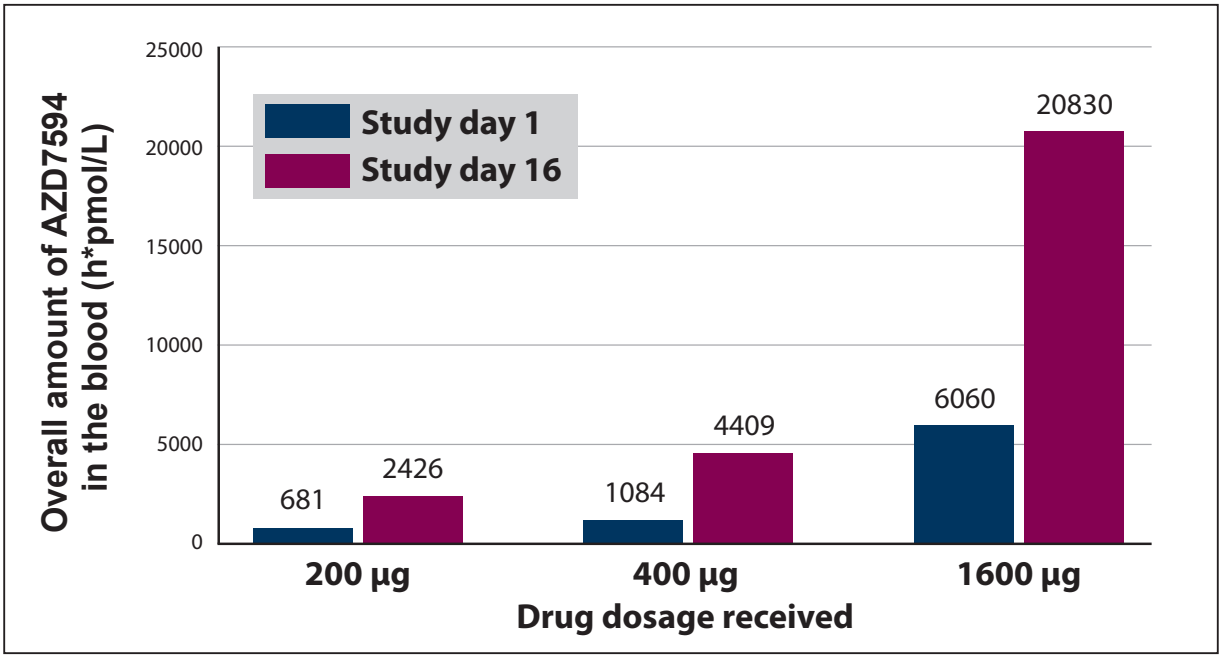
Researchers measured the highest amount of AZD7594 in participants' blood in picomoles per liter of blood (pmol/L). This is a widely accepted scientific unit of measurement. The figure below shows this amount for both Day 1 and Day 16 in the study.



How long it took for AZD7594 to reach its highest amount in the blood
Researchers measured in hours (h) the time it took for AZD7594 to reach its highest amount in participants' blood. The figure below shows this time for both Day 1 and Day 16 in the study.



Overall amount of AZD7594 in the blood
Researchers measured the overall amount of AZD7594 in participants' blood in picomole hours per liter of blood (h*pmol/L). The figure below shows this amount for both Day 1 and Day 16 in the study.



Overall, researchers found the following:

- Generally, AZD7594 was taken up into the blood and then slowly removed from the body.
- After 8 days of treatment, AZD7594 reached steady levels in the blood.
- How AZD7594 acted in the body was dependent on the dose. The higher the dose, the higher the average and highest amount of AZD7594 in the blood, and the longer it took for AZD7594 to leave the body.
- There was very little AZD7594 removed from the body through the urine.

How was the body affected by AZD7594?

Researchers also wanted to know how the body was affected by AZD7594. Researchers measured the levels of 2 hormones called cortisol and DHEAS, as well as a protein called osteocalcin, in participants' blood. These hormones and protein are related to the glucocorticoid system in the body. Researchers found:

- There was no difference in cortisol levels between the placebo and AZD7594 groups on Day 1. On Day 16, participants in the 1600 µg AZD7594 group had the highest difference in cortisol levels compared to the placebo group.
- Average DHEAS levels were similar between Day 1 and Day 16 in the placebo group. In the 200 µg AZD7594 and 400 µg AZD7594 groups, average DHEAS levels were slightly lower on Day 16 than on Day 1. In the 1600 µg AZD7594 group, average DHEAS levels were slightly higher on Day 16 than on Day 1.
- There was no difference in osteocalcin levels between the placebo and AZD7594 groups throughout the study.

What medical problems did participants have?

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". These medical problems may or may not be caused by the study drug.

How many participants had medical problems in the study?

The table below shows how many participants in each treatment group developed medical problems. No participants stopped taking the study drugs because of a medical problem.

	Placebo (Out of 6 participants)	AZD7594 200 µg (Out of 7 participants)	AZD7594 400 µg (Out of 7 participants)	AZD7594 1600 µg (Out of 7 participants)
How many participants developed medical problems?	1 (16.7%)	3 (42.9%)	1 (14.3%)	1 (14.3%)

How many participants developed serious medical problems?

A medical problem is considered serious when it is life-threatening, causes lasting problems, or requires hospital care. No participants died during this study, and no participants developed serious medical problems.

What were the medical problems in the study?

The table below shows the medical problems that happened to at least 1 participant in the study.

	Placebo (Out of 6 participants)	AZD7594 200 µg (Out of 7 participants)	AZD7594 400 µg (Out of 7 participants)	AZD7594 1600 µg (Out of 7 participants)
Dry throat	0	1 (14.3%)	0	0
Stuffy nose	0	1 (14.3%)	0	0
Pain in the upper part of the throat	0	1 (14.3%)	0	0
Folliculitis (infection of hair follicles)	0	0	1 (14.3%)	0
Gout (swelling of joints caused by having too much uric acid in the blood)	1 (16.7%)	0	0	0
Lightheadedness	0	0	0	1 (14.3%)

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/NCT02645253.

Official study title: A Study to Assess the Safety, Tolerability and Pharmacokinetics of AZD7594 Inhaled Formulation in Healthy Japanese Men

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 trial. 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 trials.

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