Clinical trial results

AstraZeneca

Research Sponsor:	AstraZeneca
Drugs Studied:	AZD8871
National Clinical Trial #:	NCT02814656
Eudra CT #:	2016-000776-14
Protocol #:	D6640C00003
Study Date:	June 2016 to November 2016
Short Study Title:	A study in healthy male volunteers to investigate a new drug for the treatment of chronic obstructive pulmonary disease and possibly other lung diseases like asthma

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 AZD8871. This drug is being developed to treat chronic obstructive pulmonary disease, also called COPD, and possibly other lung diseases like asthma. You and all of the other participants helped researchers learn if AZD8871 causes any medical problems and how it acts in the body.

AstraZeneca, 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 organisation called CISCRP prepared this summary of the study results for you with the help of a medical writing organisation. 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 June 2016 and ended in November 2016. It included 24 participants at 1 study site in the United Kingdom. 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 patients can take a new drug, 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, AZD8871, is being developed to treat COPD and possibly other lung diseases like asthma. COPD is a lung disease that causes a chronic inflammation of the lungs that creates a blockage of the airways and makes it difficult to breathe. Asthma is a lung disease that can cause coughing, wheezing, chest tightness, and difficulty breathing. COPD and asthma are both diseases that make it hard to breathe.

In this study, researchers wanted to see if AZD8871 causes any medical problems, how AZD8871 acted in the body, and how long it took for AZD8871 to reach steady levels in the blood. A drug reaches a steady level in the blood when the amount of the drug going into the body is the same as the amount of the drug that the body gets rid of.

Researchers compared 3 different doses of AZD8871 to a placebo. A placebo looks like the study drug but contains no real medicine. Researchers use placebos in studies to compare the results for participants who get study drugs with the results for participants who get no medicine at all. Researchers wanted to know:

- What medical problems did participants have after they got AZD8871?
- How did AZD8871 act in the body?
- How long did it take for AZD8871 to reach steady levels in the blood?

What kind of study was this?

Your study was a "single-blind" study. This means that none of the participants knew which treatment each participant got but the study staff did. In this study, participants got either the study drug or the placebo. Your study included 24 healthy male volunteers who were 18 to 55 years old.

What happened during the study?

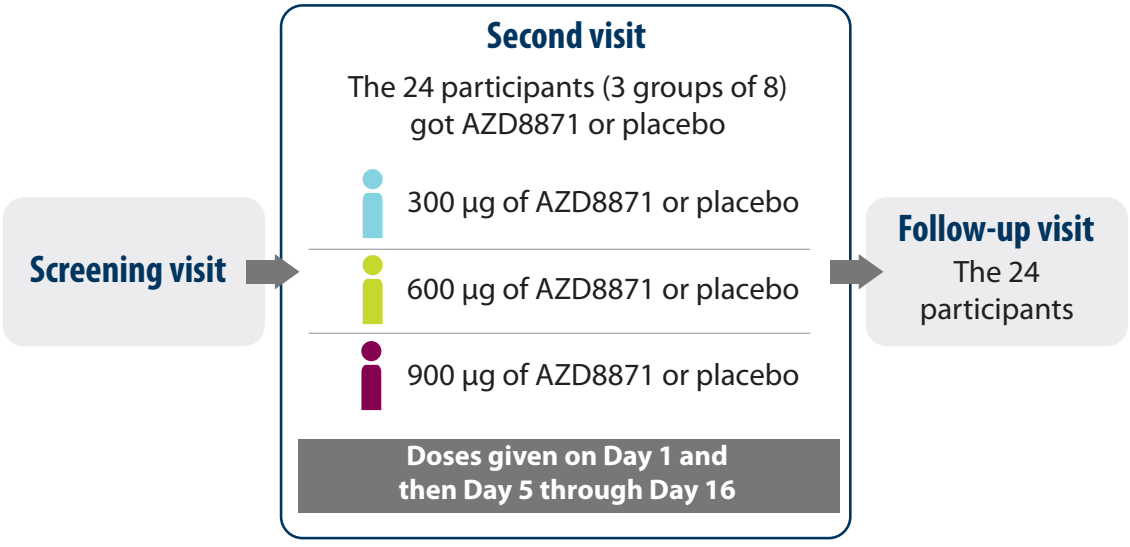
You and the other participants were in the study for up to about 8 weeks and visited the study site 3 times.

The first visit was a screening visit to make sure you and the other participants were healthy enough to take part in the study. Study doctors did a physical exam, took blood and urine samples, and did other tests to make sure you and the other participants could join the study.

During the second visit, you and the other participants got doses of AZD8871 or the placebo. You and the other participants stayed at the study site for 21 days. You got doses on Day 1 and then again from Day 5 to Day 16.

The third visit happened 5 to 7 days after the second visit, so the study doctors and staff could follow up with you to make sure you were still healthy.

The figure below shows how the study was done.



The study had 3 groups, with 8 participants in each. Each participant was in only 1 of the 3 groups. Participants in all 3 groups got either AZD8871 or the placebo through an inhaler. The different doses of the study drug and placebo were given in micrograms, or µg. This is a widely accepted scientific unit of measurement. Study doctors looked at the results of the AZD8871 doses in each group before deciding what dose to give the participants in the next group.

- Group 1: On Day 1, 6 participants got 300 µg of AZD8871 and 2 participants got the placebo. From Day 5 to Day 16, all 8 participants then got the same dose of AZD8871 or the placebo once daily.
- Group 2: On Day 1, 6 participants got 600 µg of AZD8871 and 2 participants got the placebo. From Day 5 to Day 16, all 8 participants then got the same dose of AZD8871 or the placebo once daily.
- Group 3: On Day 1, 6 participants got 900 µg of AZD8871 and 2 participants got the placebo. From Day 5 to Day 16, all 8 participants then got the same dose of AZD8871 or the placebo once daily.

It was determined by chance, like rolling dice, which treatment each participant got.

During the study, doctors checked each participant's blood pressure, heart rate, and temperature. They also tested participants' blood and urine to check their health. Finally, study doctors checked participants' hearts using an electrocardiogram, or ECG. Study doctors also asked participants how they were feeling.

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 AZD8871 are ongoing.

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 researchers keep track of all medical problems that participants had 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?

During this study, 13 out of 24 participants (54.2%) developed medical problems. No participants left the study because of medical problems.

Medical problems in the study

	300 µg of AZD8871 (out of 6 participants)	600 µg of AZD8871 (out of 6 participants)	900 µg of AZD8871 (out of 6 participants)	Placebo (out of 6 participants)
How many participants developed medical problems?	3 (50.0%)	1 (16.7%)	5 (83.3%)	4 (66.7%)

How many participants developed serious medical problems?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospitalisation. No participants developed serious medical problems during this study. No participants died during this study. No new safety concerns were raised during this study.

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

The table on the next page shows the most common medical problems that were not considered serious that occurred in more than 1 participant in each treatment group in the study.

The medical problem that researchers thought was possibly related to the study drug was headache.

Most common medical problems in the study that were not considered serious

	AZD8871 (out of 18 participants)	Placebo (out of 6 participants)
Bruising around the site of a blood draw	3 (16.7%)	2 (33.3%)
Headache	3 (16.7%)	0 (0.0%)
Common cold	2 (11.1%)	0 (0.0%)

How did AZD8871 act in the body?

Researchers wanted to learn how the study drug acted in the body. They wanted to know:

- The average amount of AZD8871 in the blood
- The highest amount of AZD8871 in the blood
- How long it took for AZD8871 to reach its highest amount in the blood
- How long it took for AZD8871 to reach steady levels in the blood

The average amount of AZD8871 in the blood

Researchers measured the average amount of AZD8871 in participants' blood for the 3 study drug doses of 300 µg, 600 µg, and 900 µg on both Day 1 and Day 16.

Overall, researchers found the following:

- On Day 1, higher doses of AZD8871 led to participants having larger average amounts of the study drug in their blood.
- On Day 16, higher doses of AZD8871 led to participants having larger average amounts of the study drug in their blood. As researchers expected, all 3 average amounts for the 300 µg, 600 µg, and 900 µg doses were higher on Day 16 than they were on Day 1.

On both days, the average amount of AZD8871 in the blood increased as the dose increased.

The highest amount of AZD8871 in the blood
Researchers measured the highest amount of AZD8871 in participants' blood for the 3 study drug doses of 300 µg, 600 µg, and 900 µg on both Day 1 and Day 16.

Overall, researchers found the following:

- On Day 1, the higher doses of AZD8871 led to participants having the highest amounts of the study drug in their blood.
- On Day 16, the higher doses of AZD8871 led to participants having the highest amounts of the study drug in their blood. The highest amount of the study drug in the blood for the doses of AZD8871 didn't increase on Day 16 compared to Day 1.

On both Day 1 and Day 16, the highest amount of AZD8871 in the blood generally increased as the dose increased.

How long it took for AZD8871 to reach its highest amount in the blood
Researchers measured how long it took for AZD8871 to reach its highest amount in the blood for the 3 study drug doses of 300 µg, 600 µg, and 900 µg on both Day 1 and Day 16.

Overall, researchers found the following:

- On Day 1, it took about 1.5 hours for all 3 doses of AZD8871 to reach their highest amount in participants' blood.
- On Day 16, it also took about 1.5 hours for all 3 doses of AZD8871 to reach their highest amount in participants' blood.

How long it took for AZD8871 to reach steady levels in the blood
Researchers measured how long it took for AZD8871 to reach steady levels in the blood. By Day 12, the amount of AZD8871 in the blood remained at a steady level.

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 https://www.clinicaltrials.gov/ct2/show/study/NCT02814656.

Official study title: A Phase I, Single Centre, Randomised, Single Blind, Placebo Controlled Study to Investigate the Safety, Tolerability and Pharmacokinetics of Multiple Ascending Doses of Inhaled AZD8871 in Healthy Male Subjects

The phone number for the AstraZeneca Information Centre 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 act is one which is performed anonymously, giving when you do not know whether you will get direct personal benefit.

This is the act that you have performed 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 your participation in clinical research.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

The Centre for Information & Study on Clinical Research Participation (CISCRP) is a non-profit organisation 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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