Clinical Trial Results

AstraZeneca

Research sponsor: AstraZeneca AB

Drug studied: AZD8871

Short study title: A study to learn if AZD8871 helps people with chronic obstructive pulmonary disease

Thank you!

Thank you for taking part in the clinical study for the drug AZD8871. You and all of the participants helped researchers learn more about AZD8871 to help people with chronic obstructive pulmonary disease, also known as COPD.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study with you and the public. An independent, non-profit organization called CISCRP and a medical writing organization called Synchrogenix helped prepare this summary of the study results. 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 doctor or staff at your study site.

What is happening with the study now?

You and the other participants were in the study for up to about 4 months. But the entire study took about 9 months to finish. The study started in December 2016 and ended in August 2017.

The study included 42 participants at 2 study sites in Germany and the United Kingdom. Even though 42 participants joined this study, only 31 participants completed the study. Researchers could not always use the information from the participants who did not complete the study. This means that some of the results in this summary are only from 31 participants.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

Why was the research needed?

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

COPD is a lung disease that causes inflammation and narrowing of the airways, which can make it difficult to breathe.

In this study, the researchers wanted to find out if AZD8871 works in participants with COPD. They also wanted to find out if participants had any medical problems during the study.

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

- How much air could participants exhale after taking different doses of AZD8871?
- Did the COPD symptoms of participants improve after taking AZD8871?
- How did AZD8871 act in the body?
- What medical problems did participants have during the study?

To answer the questions in this study, the researchers asked for the participation of men and women with COPD. The participants in this study were 49 to 79 years old.

What kind of study was this?

This was a “double-blind” study. This means that none of the participants, doctors, or other staff knew which treatment each participant took. This was also a “crossover” study. This means that all participants took each treatment but in a different order.

In this study, all participants took AZD8871 and a placebo. 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 participants who take the drug are actually caused by the drug.

A computer program was used to randomly choose the order in which participants took each treatment. 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.

When the study ended, the sponsor found out which treatment each participant took. This allowed the sponsor to compare the results from participants in the different treatment groups.

What happened during the study?

To see if participants could join the study, doctors asked about the medications they were taking and their medical history. Study doctors also did a physical examination to check the overall health of participants and asked how they were feeling.

During the study, there were 3 treatments and three 14-day treatment periods. All participants took all 3 treatments. During each of the 3 treatment periods, participants took 1 of the 3 treatments below once daily through an inhaler for 14 days:

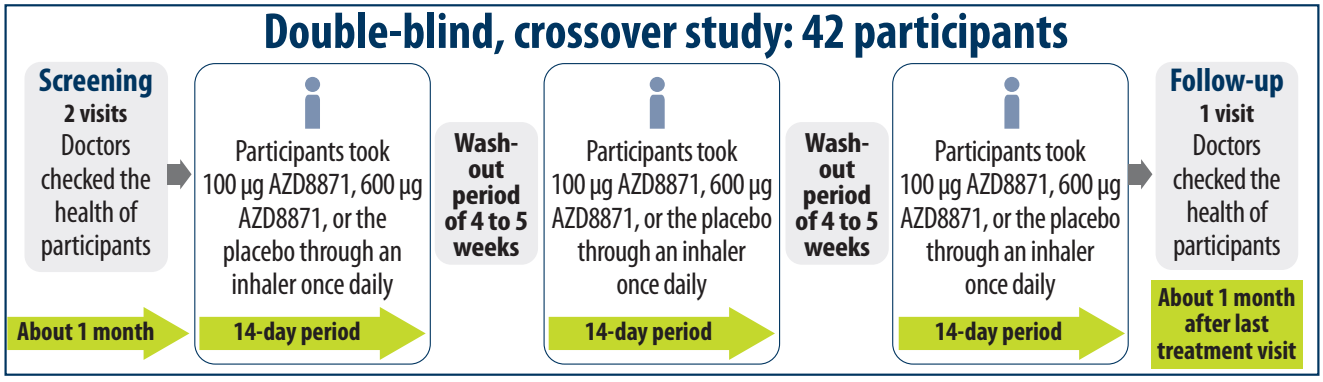
- 100 micrograms, also known as µg, of AZD8871
- 600 µg of AZD8871
- the placebo

The participants visited their study site up to 12 times during this study.

Between taking each treatment, there was a "wash-out period" that lasted about 4 to 5 weeks. Participants were not allowed to take certain medications during this time. This was done so that all medications and the treatments they took before the next treatment would be "washed out" of their bodies.

At the end of the study, the participants went back to their study site for another visit. Study doctors did a physical examination to check the overall health of participants again.

The chart below shows how the study was done.



What were the study results?

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. If a full report of the study results is available, it can also be found on these websites.

How much air could participants exhale after taking different doses of AZD8871?

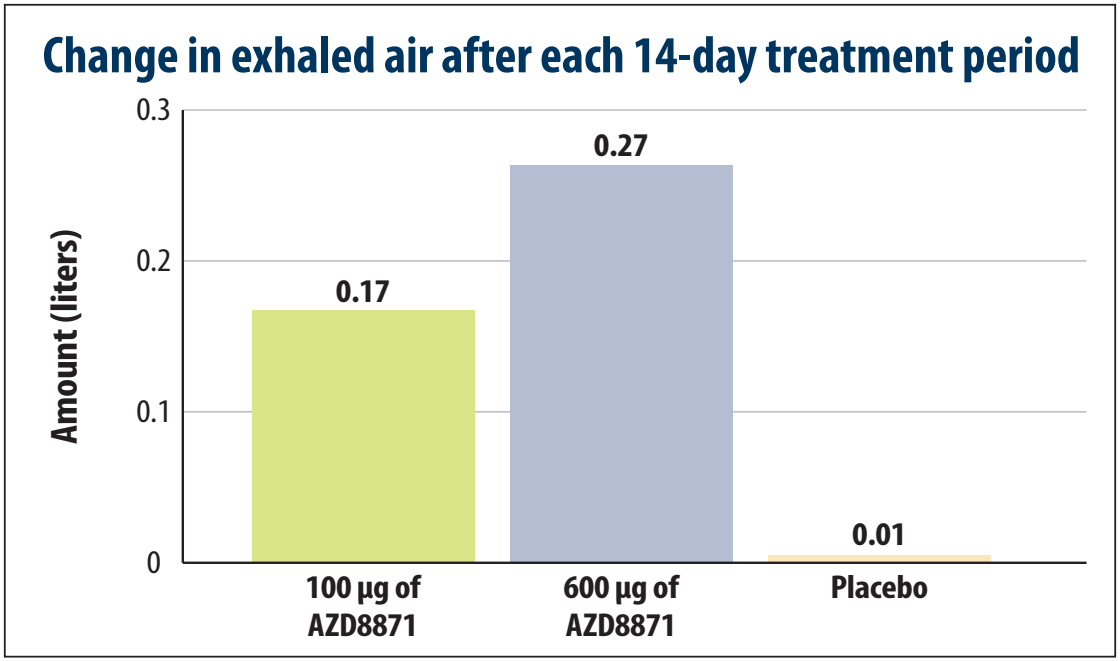
The researchers measured how much air the participants could exhale at the beginning of the study and compared those results to how much they could exhale after each 14-day treatment period.

In general, the participants could exhale more air after they took AZD8871 compared to when they took the placebo.

On average, the participants:

- could exhale 0.17 more liters of air after taking 100 µg of AZD8871
- could exhale 0.27 more liters of air after taking 600 µg of AZD8871
- could exhale 0.01 more liters of air after taking the placebo

The chart below shows these results.



Did the COPD symptoms of participants improve after taking AZD8871?

The researchers also wanted to find out if AZD8871 helped improve COPD symptoms in participants. So, they gave the participants a survey that asked them to grade how severe their COPD symptoms were at different times during the study. A decrease in score meant that their COPD symptoms had improved.

On average, the participants taking:

- 100 µg of AZD8871 had a score decrease that was 0.46 points lower than when they took the placebo
- 600 µg of AZD8871 had a score decrease that was 1.16 points lower than when they took the placebo

How did AZD8871 act in the body?

The researchers also wanted to find out how much AZD8871 entered the body of participants and how long it stayed there. So, they took blood samples from the participants at different times during the study and measured the amounts of AZD8871 in the blood.

After each 14-day treatment period, the researchers generally found that:

- The average amount of AZD8871 in the blood was greatest when the participants took the higher dose of AZD8871
- The highest amount of AZD8871 in the blood was also greatest when the participants took the higher dose of AZD8871
- It took a similar amount of time for both AZD8871 doses to reach their highest amount in the blood

What medical problems did participants have?

This section is a summary of the medical problems participants had during the study that the 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.

The adverse reactions that happened in this study 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. The websites listed at the end of this summary may have more information about the adverse reactions that happened in this study.

Even though 42 participants joined this study, only 31 participants completed the study. Researchers could not always use the information from the participants who did not finish the study. This means that some of the results in this summary are only from 31 participants.

How many participants had serious adverse reactions?

None of the participants in this study had serious adverse reactions. None of the participants died during this study.

How many participants had adverse reactions?

In this study, about the same number of participants in each treatment group had adverse reactions.

There were 11.9% of participants who had adverse reactions during this study. This happened in 5 of 42 participants.

There were 5.9% of participants who had adverse reactions while taking 100 µg of AZD8871. This happened in 2 of 34 participants.

There were 5.1% of participants who had adverse reactions while taking 600 µg of AZD8871. This happened in 2 of 39 participants.

There were 2.8% of participants who had adverse reactions while taking the placebo. This happened in 1 of 36 participants.

None of the participants left the study because of adverse reactions.

What adverse reactions did participants have?

The most common adverse reaction was headache.

The table below shows the adverse reactions that happened during this study.

Adverse reactions during this study

	100 µg of AZD8871 (Out of 34 participants)	600 µg of AZD8871 (Out of 39 participants)	Placebo (Out of 36 participants)
Headache	5.9% (2)	2.6% (1)	2.8% (1)
Sudden need to urinate	2.9% (1)	0.0% (0)	0.0% (0)
Worsening of COPD	0.0% (0)	2.6% (1)	0.0% (0)

How has this study helped patients and researchers?

The results presented here are from a single study. These results helped researchers learn more about AZD8871, if it helps patients with COPD, how it acts in the body, and if it is safe to take.

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 changes in treatment.

Further clinical studies with AZD8871 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 **"NCT02971293"** into the search box called **"Other Terms"** and click **"Search all studies"**.
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home & Search"**. Then, type **"2016-002863-32"** in the search box and click **"Search"**.

The full title of your study is: A phase IIa, randomised, multi-centre, double-blind, placebo-controlled, 3 periods, crossover study to investigate the efficacy, pharmacokinetics, safety and tolerability of inhaled AZD8871 administered once daily for 2 weeks in patients with moderate to severe COPD

The protocol number of your study is: D6640C00004

AstraZeneca AB sponsored this study and has its headquarters at Astraallén, 152 57 Södertälje, Sweden.

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.