

Research Sponsor: AstraZeneca AB

Drug Studied: AZD5634

Short Study Title: A study to learn if AZD5634 helps remove mucus from the lungs of people with cystic fibrosis and is safe to take

Thank you!

Thank you to the participants who took part in the clinical trial for the study treatment AZD5634.

AstraZeneca sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISC RP helped prepare this summary of the study results.

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?

The study started in May 2017 and ended in April 2018. It included participants in the United States.

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?

Researchers are looking for a way to help people with cystic fibrosis breathe better. Before a treatment can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

Cystic fibrosis affects the body's ability to move salt and water in and out of cells. This makes the lungs and pancreas give off a thick mucus. The mucus sticks to the lungs and airways, which makes it hard to breathe.

Researchers think that AZD5634 helps remove mucus from the lungs by stopping the movement of salt in the lungs. The researchers in this study wanted to find out if AZD5634 helped participants breathe better by removing mucus from the lungs. The researchers also wanted to find out if the participants had any medical problems during the study.

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

- How much mucus did AZD5634 help remove from the lungs?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done that help find out if AZD5634 improves the health of people with cystic fibrosis.

In this study, the researchers asked for the help of people with cystic fibrosis.

What kind of study was this?

This was a “double-blind” study. This means none of the participants nor the researchers knew which treatment the participants took.

Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. When the study ended, the research sponsor found out which treatment each participant took so they could create a report of the study results.

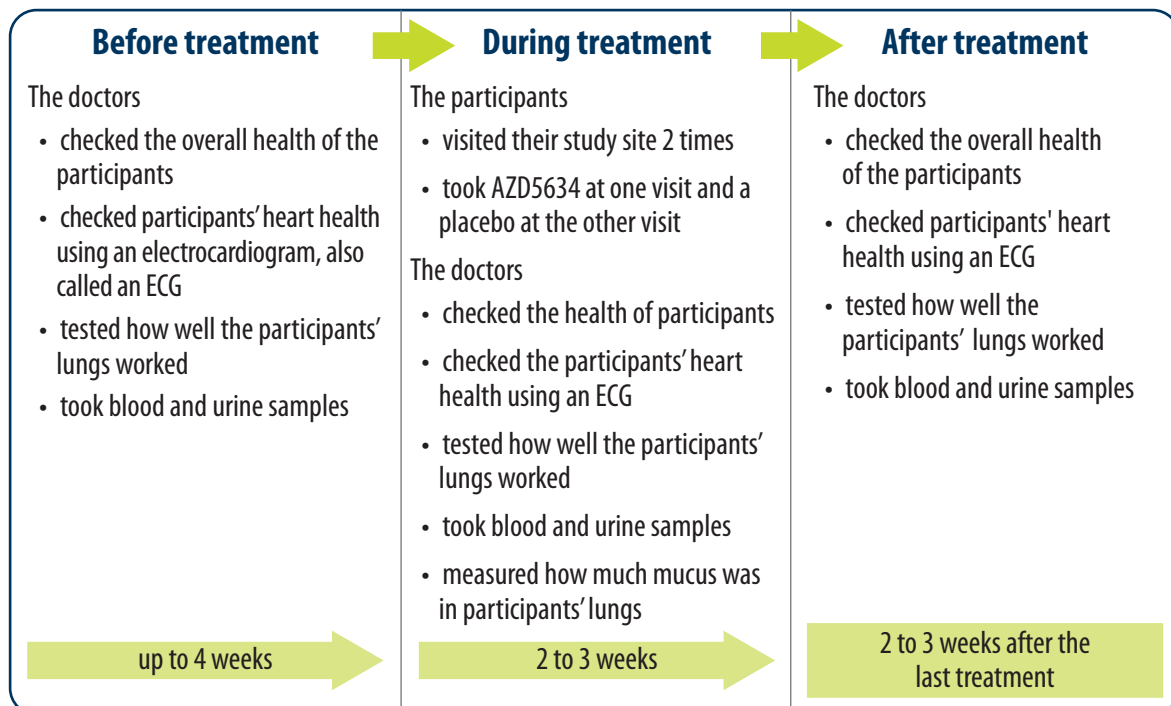
All of the participants in the study took 1 dose of AZD5634 and 1 dose of a placebo. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the treatment are actually caused by the treatment.

The participants took AZD5634 and the placebo 2 to 3 weeks apart. They took both treatments using an inhaler. The dose of AZD5634 was 612 micrograms, also called µg.

A computer program was used to randomly choose the order of the treatment each participant took. 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.

What happened during the study?

The figure below shows how the study was done.



What were the results of the study?

This is a summary of the main results from the study overall. The results each participant had might be different and are not in this summary.

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 treatment change.

The website listed at the end of this summary may have a full report of the study results.

How much mucus did AZD5634 help remove from the lungs?

The researchers found that 1 hour after taking AZD5634, it did not remove any more mucus from the lungs than the placebo.

To learn how much mucus was removed, the doctors asked the participants to inhale particles after each treatment. Then the doctors scanned the lungs to measure the level of particles. They did this about 11 times after the participants inhaled the particles. By measuring how much the level of particles in the lungs went down, the researchers were also able to measure how much mucus was removed after 1 hour.

What medical problems did the participants have during the study?

This section is a summary of the medical problems the participants had during the study that the study doctors thought might be related to the study. The medical problems participants have during clinical studies that the doctors think might be related to the study drug are called “adverse reactions”.

The adverse reactions that happen in a study may or may not be caused by the study treatment. A lot of research is needed to know whether a treatment causes an adverse reaction.

The website listed at the end of this summary may have other information about adverse reactions or other medical problems that happened during this study.

How many participants had adverse reactions?

There were participants who had adverse reactions during the study.

None of the participants stopped taking the study treatment because of adverse reactions they had during the study.

Because there was a very small number of participants in this study, the number of participants who had these adverse reactions is not in this summary. This helps protect their identities.

What adverse reactions did participants have?

The adverse reactions that happened in this study were cough, lesser amount of air breathed out, diarrhea, and dry skin.

How has this study helped patients and researchers?

The results presented here are for a single study in patients with cystic fibrosis. These results helped the researchers learn if AZD5634 helped remove mucus from the lungs of the participants and how safe it was to inhale AZD5634.

Researchers look at the results of many studies to decide which treatments work best and are safest. This summary shows only the main results from this one study. Other studies may provide new information or different results.

Further clinical studies with AZD5634 are planned.

Where can I learn more about this study?

You can find more information about this study on the website listed below. If a full report of the study results is available, it also can be found here.

- www.AstraZenecaClinicalTrials.com. Once you are on the website, type “**D6600C00002**” into the search box, and click “**Find a Study**”.

Full trial title: A Phase Ib Randomized Blinded Placebo-Controlled, Cross-Over Study to Assess the Effect of AZD5634 on Mucociliary Clearance as Well as Safety, Tolerability, and Pharmacokinetic Parameters Following Single Inhaled Dose Administration to Patients with Cystic Fibrosis

Protocol number: D6600C00002

AstraZeneca sponsored this study and has its headquarters at 1800 Concord Pike in Wilmington, Delaware.

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 participants.



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 studies, nor is it involved in conducting clinical studies.

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