

Clinical Study Results



Research Sponsor: AstraZeneca AB

Drug studied: AZD9898

Study Title: A study in healthy volunteers and people with asthma to evaluate different doses of AZD9898

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD9898.

AstraZeneca AB sponsored this study and thinks it is important to share the results. An independent non-profit organization called CISCRP 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 August 2017. It included 34 participants from the United Kingdom.

The researchers planned to include 3 parts in the study. Parts 1 and 3 would include only healthy participants. Part 2 would include people with asthma. But after researchers reviewed the results from Part 1, they learned that the study did not have the results that were expected. Researchers decided not to continue with Parts 2 and 3 of the study. This meant that only healthy participants were included in this study.

The sponsor reviewed the information 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 better way to treat people with asthma. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and if it works. This includes testing in healthy volunteers as well as people with the condition being studied.

Asthma is a condition that can cause swelling in the tubes that carry air in and out of the lungs. This swelling can make it difficult for people with asthma to breathe. They can also experience wheezing, chest tightness and coughing.

In this study, the researchers wanted to find out how AZD9898 acted in the body. Researchers think AZD9898 can stop the process of swelling in the breathing tubes. AZD9898 is also expected to speed up the recovery from the symptoms of asthma.

The main question the researchers wanted to answer in this study was:

- What medical problems did the participants have during the study?

The answer to this question is important to know before other studies can be done that help find out if AZD9898 improves the health of people with asthma.

The researchers asked for the help of healthy men and women. Everyone in the study was between 18 and 50 years old when they joined.

What kind of study was this?

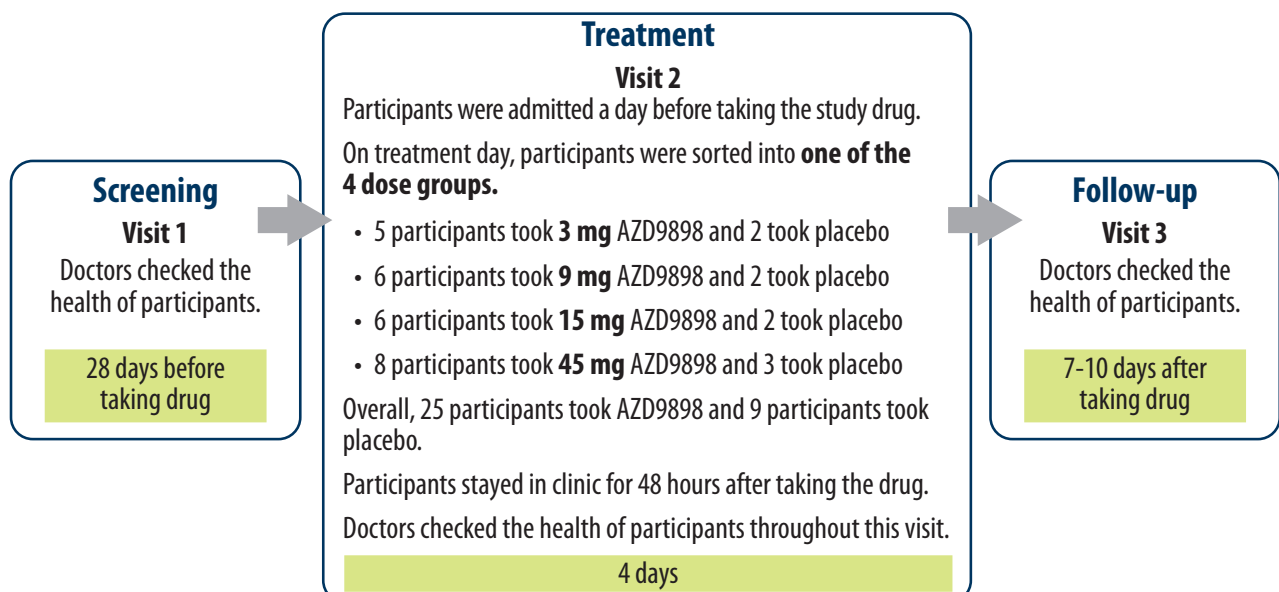
This study was a “single-blind” study. This means the researchers knew what participants were taking but the participants did not. In this study, participants took either AZD9898 or a placebo. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the study drug are actually caused by the study drug. The study tested different doses of AZD9898 measured in milligrams, called “mg” for short. The lowest dose tested was 3 mg and the highest was 45 mg.

A computer program was used to randomly choose 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 chart below shows how Part 1 was done.

Part 1. Single-blind study: 34 participants



What were the results of the study?

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.

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

What medical problems did 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 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.

These adverse reactions 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 other information about adverse reactions or other medical problems that happened during this study.

How many participants had serious adverse reactions?

In this study, none of the 34 participants had a serious adverse reaction.

How many participants had adverse reactions?

There were 2.9% of participants who had adverse reactions during the study. This was 1 out of 34 participants.

None of the participants stopped taking AZD9898 because of adverse reactions during the study.

What adverse reactions did the participants have?

The adverse reactions that happened in this study were headache and nosebleed.

This happened in 1 out of 25 participants that took AZD9898. This was 4% of participants that took AZD9898. This participant took the highest dose of AZD9898.

None of the 9 participants who took the placebo had an adverse reaction.

How has this study helped patients and researchers?

The results shown in this summary are for this single study. These results helped researchers learn how AZD9898 works in healthy participants.

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. However, further clinical studies with AZD9898 in participants with asthma are not currently 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 “**NCT03140072**” into the search box and click “**Search**”.
- www.clinicaltrialsregister.eu. Once you are on the website, click “**Home and Search**”. Then type “**EU Clinical Trial # 2016-004237-24**”. Then click “**Search**”.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type “**D7620C00001**” into the search box and click “**Find a Study**”.

The full title of your study is: A phase 1, randomized, placebo-controlled study to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and food effect of single and multiple ascending oral doses of AZD9898 in healthy volunteers and asthma patients.

National Clinical Trial number: NCT03140072

AstraZeneca Protocol number: D7620C00001

AstraZeneca AB sponsored this study and has its headquarters in 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 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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