

Clinical Study Results



Research Sponsor: AstraZeneca

Drug Studied: AZD1419

Study Title: A study to learn more about using AZD1419 to treat people who have asthma, and if AZD1419 is safe to take

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD1419. All the participants helped researchers learn more about using AZD1419 as treatment for people who have asthma.

AstraZeneca sponsored this study and thinks it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their 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?

The participants were in the study for up to about 1 year. But the entire study took about 2 years to finish.

The study started in October 2016 and ended in September 2018.

The study included 81 participants in Denmark, Hungary, Poland, and Sweden.

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

Why was the research needed?

Asthma is a disease that can cause swelling in the lungs. This swelling can lead to several symptoms, such as chest pain, coughing, and difficulty breathing. Currently, there is no cure for this disease.

Researchers are looking for a better way to treat people who have asthma. 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.

The researchers in this study wanted to learn if the study drug, AZD1419, could help control the participants' asthma and decrease their symptoms. The researchers also wanted to know if AZD1419 could help decrease how often the participants needed to take their asthma treatments, and if they had any medical problems during the study.

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

- Can AZD1419 help control asthma?
- Can AZD1419 help decrease asthma symptoms?
- What medical problems did the participants have during the study?

To answer the questions in this study, the researchers asked for the help of men and women who have asthma. The participants in this study were 24 to 76 years old when they joined.

What kind of study was this?

This was a “double-blind” study. This means none of the participants, doctors, or other study staff knew what treatment each participant 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 the participants took so they could create a report of the study results.

In this study, the participants took either AZD1419 or a placebo treatment through an inhaler. A placebo treatment looks like a drug treatment but does not have any medicine in it. Researchers use placebo treatments to help make sure that any of the effects they see in the participants who take the study drug treatment are caused by the study drug. The doses of AZD1419 were measured in milligrams, also called mg.

The participants also took their normal asthma treatments at the beginning of the study. But after 6 weeks, these treatments were slowly decreased and then stopped. This was done so that the participants could safely stop taking their normal asthma treatments.

During the study, the participants were also allowed to take an asthma treatment if they experienced a worsening of their asthma. This was called a “rescue treatment”. A rescue treatment is a treatment chosen by study doctors for participants take to help manage their asthma. Doctors use rescue treatments in studies if they think it can help participants manage their disease without affecting the study results.

A computer program was used to randomly choose the study 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?

Before the participants took study treatment, they visited their study site 2 times over the course of 4 weeks. At the first of these visits, the study doctors checked to make sure the participants could join the study.

The study doctors:

- did a physical examination
- took blood and urine samples
- checked the participants’ heart health by using a medical scan called an electrocardiogram, also called an ECG
- checked the participants’ lung health, asthma symptoms, and overall health
- asked the participants about their medical history, how they were feeling, and what asthma treatments and other medicines they were taking

During the second visit, the participants who could join the study received study equipment. They used the equipment throughout the study to record their asthma symptoms, record any swelling in the lungs that happened, and measure how well their lungs were working.

During the study, there were 2 parts, called the “treatment period” and the “observation period”. Throughout both parts, the study doctors:

- checked the participants’ lung health, asthma symptoms, and overall health
- checked the participants’ surveys that asked them about their asthma symptoms and how they felt

During the treatment period, the participants visited their study site 13 times over the course of 12 weeks. They continued taking their normal asthma treatments at first during this time period, but these treatments were slowly decreased and then stopped.

During these 12 weeks, the participants inhaled either AZD1419 or the placebo treatment 13 times. For the first 4 treatments of AZD1419, the dose was 4 mg.

The researchers carefully studied the results and checked the health of the participants to decide what the next doses should be. For each of the next 9 treatments, the participants inhaled 1 of the below doses:

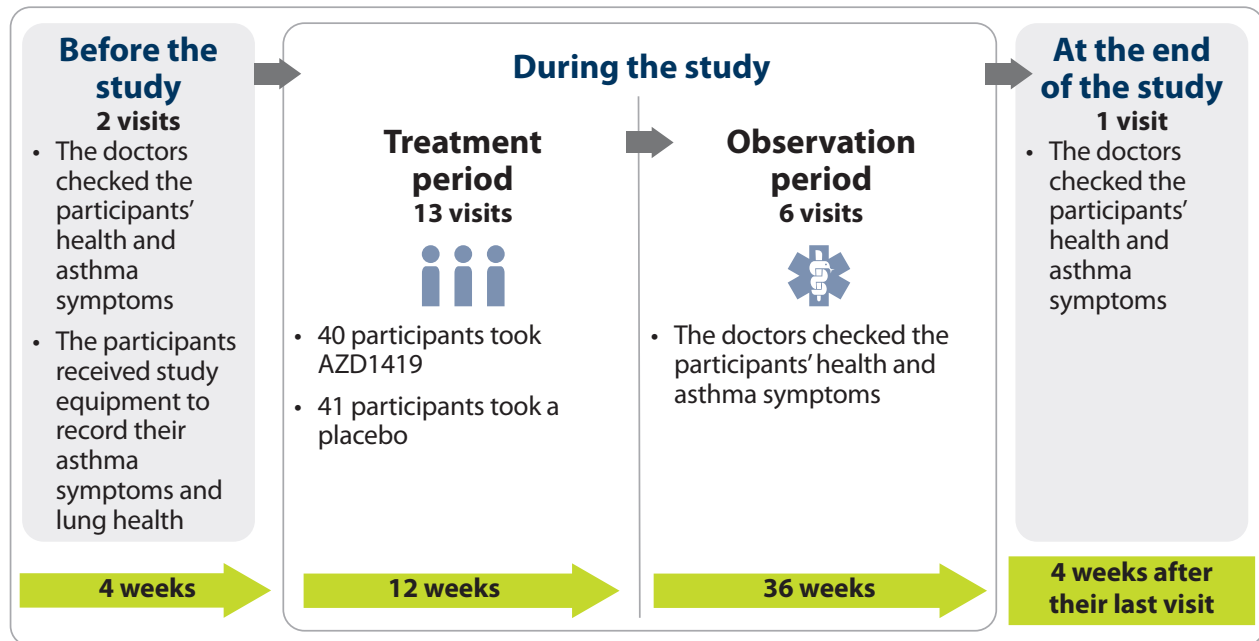
- 1 mg of AZD1419
- 4 mg of AZD1419
- 8 mg of AZD1419

After the participants took these last 9 treatments, the observation period of the study started.

During the observation period, the participants visited their study site 6 times over the course of 36 weeks. At these visits, the study doctors continued to check the participants’ lung health, asthma symptoms, and overall health. They also gave the participants more surveys that asked them about their asthma symptoms and how they felt.

At the end of the study, the participants visited their study site 1 time 4 weeks after their last observation period visit. At this visit, the study doctors checked the participants’ lung health, asthma symptoms, and overall health.

The chart below shows how the study was done.



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. A full list of the questions the 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.

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 changes.

Can AZD1419 help control asthma?

No. Overall, the researchers found that the AZD1419 treatment did not help control participants' asthma compared to the placebo treatment.

To answer this question, the researchers compared the number of participants in both treatment groups who experienced a worsening of their asthma during the study.

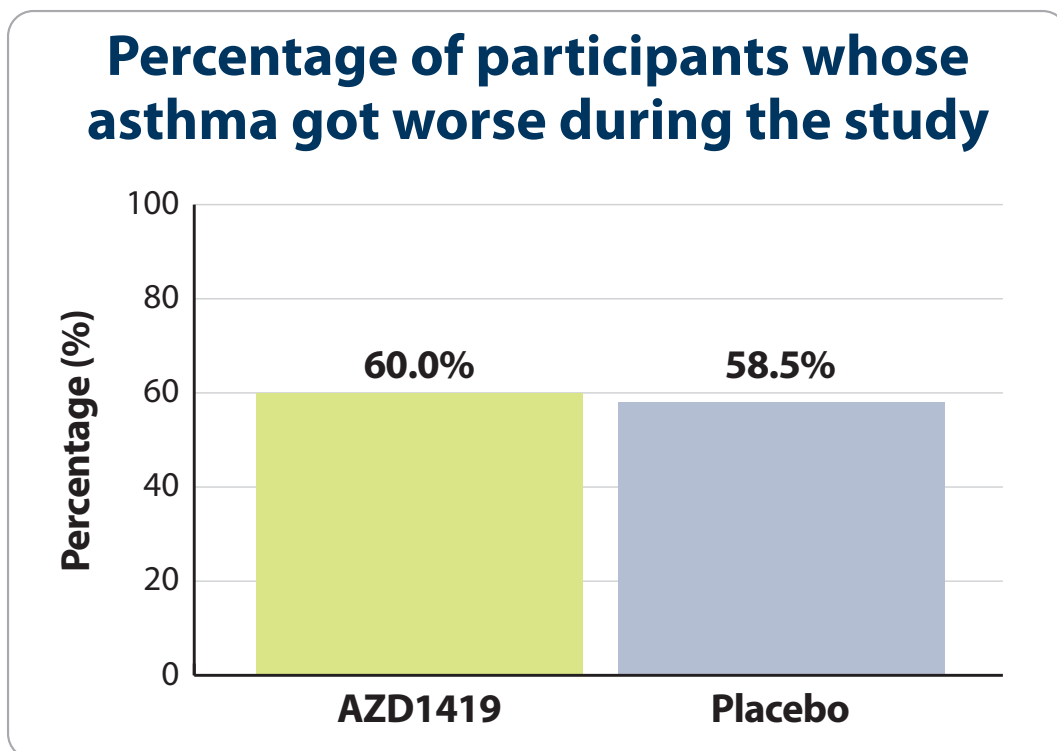
Participants were considered to have experienced a worsening of their asthma if any of the below events happened before the end of the study:

- a general worsening of asthma symptoms
- increased difficulty breathing
- increased need for asthma rescue treatment
- other asthma treatments were needed to help control asthma

The participants in both groups experienced a similar worsening of their asthma during the study, which meant that the AZD1419 treatment did not help control asthma compared to the placebo treatment. By the end of the study, the researchers found that:

- 60.0% of participants in the AZD1419 treatment group experienced a worsening of their asthma. This was 24 out of 40 participants.
- 58.5% of participants in the placebo treatment group experienced a worsening of their asthma. This was 24 out of 41 participants.

The figure below shows these results.



Can AZD1419 help decrease asthma symptoms?

No. Overall, the researchers found that AZD1419 treatment did not help decrease the participants' asthma symptoms compared to the placebo treatment.

To answer this question, the researchers kept track of the following throughout the study:

- how often the participants had asthma symptoms
- the severity of asthma symptoms
- the participants' survey scores about how they were feeling

The researchers compared these results throughout the study between the 2 treatment groups.

Overall, there was a small difference in asthma symptoms that all participants experienced during the study. This meant that the AZD1419 treatment did not help decrease asthma symptoms compared to the placebo treatment.

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 treatment. 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 treatment. A lot of research is needed to know whether a treatment 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?

None of the participants had serious adverse reactions during the study.

None of the participants died because of serious adverse reactions during the study.

How many participants had adverse reactions?

Overall, there were 28.4% of participants who had adverse reactions during the study. This was 23 out of 81 participants.

The table below shows how many participants had adverse reactions during the study.

Adverse reactions during the study			
	AZD1419 (out of 40 participants)	Placebo (out of 41 participants)	Total (out of 81 participants)
How many participants had adverse reactions during the study?	42.5% (17)	14.6% (6)	28.4% (23)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment because of adverse reactions?	2.5% (1)	0.0% (0)	1.2% (1)

What adverse reactions did the participants have?

The most common adverse reaction during the study was fever.

The table below shows the adverse reactions that happened in at least 5.0% of participants during the study. There were other adverse reactions that happened during the study, but these happened in fewer participants.

Most common adverse reactions during the study			
	AZD1419 (out of 40 participants)	Placebo (out of 41 participants)	Total (out of 81 participants)
Fever	22.5% (9)	2.4% (1)	12.3% (10)
Chills	15.0% (6)	2.4% (1)	8.6% (7)
Muscle pain	15.0% (6)	0.0% (0)	7.4% (6)
Difficulty breathing	10.0% (4)	0.0% (0)	4.9% (4)

How has this study helped patients and researchers?

This study helped researchers learn more about using AZD1419 to help treat people who have asthma, and about the safety of AZD1419.

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 AZD1419 are not 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 “**NCT02898662**” into the search box, and click “**Search**”.
- www.clinicaltrialsregister.eu. Once you are on the website, click “**Home and Search**”, then type “**2016-000977-19**” in the search box, and click “**Search**”.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type “**D2500C00003**” into the search box, and click “**Find a Study**”.

Full Trial Title: A Phase 2 Placebo-Controlled, Randomized, Double-Blind, Adaptive Dose Trial of the Safety and Efficacy of Inhaled AZD1419 in Adults With Eosinophilic, Moderate to Severe Asthma

AstraZeneca Protocol Number: D2500C00003

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 patients.



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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