Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD1402

Study Title: A study to understand how different forms and doses of AZD1402 act in healthy participants, and if AZD1402 is safe to take

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD1402. 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 March 2019 and ended in June 2019. The study included 18 participants in the United Kingdom.

AstraZeneca AB 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 better way to treat patients who have asthma. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

Asthma is a condition that causes a person's airways to narrow, swell, and create extra mucus. This can lead to several symptoms, including chest pain, coughing, and difficulty breathing. Currently, there is no cure for asthma.

There are several inhaled treatments that doctors use to help patients control their asthma symptoms. But these treatments may take a long time to work, and they may not help some patients.

The study drug, AZD1402, is an inhaled treatment that is being developed to help control asthma symptoms. In this study, the researchers wanted to find out how AZD1402 acts in the body when taken in different forms and doses.

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

- How did the AZD1402 treatments act in the body?
- Did the AZD1402 treatments have a taste or smell?
- 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 would further help researchers learn if AZD1402 improves the health of people who have asthma.

The researchers asked for the help of healthy men who did not have asthma. The participants in this study were between 20 and 47 years old when they joined.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participant knew which treatment the participant was taking.

There were 3 inhaled treatments in this study. Each treatment included AZD1402. The participants took all 3 treatments, but in a different order.

There were 2 forms of AZD1402: a powder and a liquid. The forms were taken in 2 ways: through an inhaler and through a nebulizer.

The powder form of AZD1402 was inhaled. The liquid form was inhaled through a nebulizer, which is a type of inhaler used to turn a liquid into a mist that enters the lungs.

A computer program was used to randomly choose the order in which the 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.

What happened during the study?

Before the participants took study treatment, they visited their study site 1 time over the course of about 4 weeks. At this visit, 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 using an electrocardiogram, also called an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking
- explained how to take the inhaled treatments during the study

During the study, the participants visited their study site 3 times over the course of about 3 weeks. During each visit, the participants stayed at their study site for 3 days and took 1 of 3 AZD1402 treatments:

- a liquid dose of AZD1402 taken through a nebulizer
- a low dose of AZD1402 taken as a powder through an inhaler
- a high dose of AZD1402 taken as a powder through an inhaler

There was a “washout period” of about 1 week in between each treatment visit. During this time, the participants did not take any study treatment. This was done so that each treatment could be “washed out” of their bodies before they took the next treatment.

About 2 weeks after taking the last treatment, the participants visited their study site 1 last time. At this visit, the study doctors checked the participants’ health and asked them how they were feeling.

What were the results of the study?

This is an overall summary of the main results from this study. The results for each participant might be different and are not included 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.

How did the AZD1402 treatments act in the body?

Overall, the researchers found that AZD1402 acted as they thought it would in the body. The researchers thought the amount of the drug in the body would be highest when the participants took the high dose of AZD1402 as a powder through an inhaler. Overall after treatment, the researchers found that this was true.

The researchers considered the dose amounts to be similar between the liquid dose of AZD1402 taken through a nebulizer and the low dose of AZD1402 taken as a powder through an inhaler. So, the researchers thought that the amount of the drug in the body would be similar when the participants took these 2 treatments. Overall after treatment, the researchers found that this was true.

To learn how AZD1402 acted in the body, the researchers took blood samples from the participants throughout the study. Then, they used several measurements to study and compare the results.

At each treatment visit, the study doctors took blood measurements. The researchers focused on the amount of AZD1402 in the blood over the 48-hour period after treatment.

This time period was chosen so that the amount of the drug in the blood was still high enough for the researchers to accurately measure.

After the participants took their treatment, the researchers studied the following measurements:

- the average amount of AZD1402 in the blood over the course of the study
- the average amount of AZD1402 in the blood over the course of the study, divided by the AZD1402 dose amount in each treatment
- the average amount of AZD1402 in the blood at the end of the first 48 hours
- the average amount of AZD1402 in the blood at the end of the first 48 hours, divided by the AZD1402 dose amount in each treatment
- the highest amount of AZD1402 in the blood over the course of the first 48 hours
- the highest amount of AZD1402 in the blood over the course of the first 48 hours, divided by the AZD1402 dose amount in each treatment

Overall after treatment, the researchers found that these amounts were highest when the participants took the high dose of AZD1402 as a powder through an inhaler. The researchers also found that these amounts were similar when the participants took the liquid dose of AZD1402 through a nebulizer and the low dose of AZD1402 as a powder through an inhaler.

Did the AZD1402 treatments have a taste or smell?

No. Overall, the participants did not think that the AZD1402 treatments had a taste or smell.

To answer this question, the study doctors gave the participants surveys throughout the study that asked them to rate the taste and smell of the AZD1402 treatments. Overall, the participants did not report a taste or smell for the AZD1402 treatments.

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 treatments. 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 treatments. 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?

There were 5.6% of participants who had serious adverse reactions during the study. This was 1 out of 18 participants. This participant had the serious adverse reaction of swelling in the lungs.

None of the participants died during the study.

How many participants had adverse reactions?

There were 55.6% of participants who had an adverse reaction during the study. This was 10 out of 18 participants. Some of the participants had more than 1 adverse reaction.

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

Adverse reactions during the study

	Liquid dose of AZD1402 taken through a nebulizer (Out of 18 participants)	Low dose of AZD1402 taken as a powder through an inhaler (Out of 18 participants)	High dose of AZD1402 taken as a powder through an inhaler (Out of 18 participants)
How many participants had adverse reactions during the study?	33.3% (6)	16.7% (3)	27.8% (5)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)	5.6% (1)
How many participants stopped treatment due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions did the participants have?

The most common adverse reaction during the study was a cough.

The table below shows the adverse reactions that happened in at least 2 participants during the study. There were other adverse reactions that happened during the study, but those happened in fewer participants.

Most common adverse reactions during the study

	Liquid dose of AZD1402 taken through a nebulizer (Out of 18 participants)	Low dose of AZD1402 taken as a powder through an inhaler (Out of 18 participants)	High dose of AZD1402 taken as a powder through an inhaler (Out of 18 participants)
Cough	11.1% (2)	5.6% (1)	22.2% (4)
Headache	5.6% (1)	5.6% (1)	5.6% (1)
Dizziness	11.1% (2)	0.0% (0)	0.0% (0)
Fever	5.6% (1)	5.6% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers understand how different forms and doses of AZD1402 act in the body, and if AZD1402 is safe to take.

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 AZD1402 are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03921268"** into the search box, and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2018-004161-14"** in the search box, and click **"Search"**.

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

- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D2912C00001"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Randomized Open-label, 3-period, 3-treatment, Crossover Study to Assess the Effect of Inhalation Device and Formulation on Pharmacokinetics Following a Single Inhaled Dose of AZD1402 in Healthy Subjects

AstraZeneca Protocol Number: D2912C00001

AstraZeneca AB sponsored this study and has its headquarters at 151 85 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.

CISCRP

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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