AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD8154

Study Purpose: This study was done to learn more about how AZD8154 acts in the blood of healthy participants when inhaled in 2 different ways

Protocol Number: D8900C00005

Thank you

Thank you for taking part in the clinical study for the study drug AZD8154.

AstraZeneca AB sponsored this study and believes it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

Who took part in this study?

The researchers asked for the help of healthy participants.

The study included 10 participants.

Why was the research needed?

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

Asthma is a long-term lung disease that causes the airways to narrow. This can make it difficult to breathe. People who have asthma attacks may wheeze, cough, and have shortness of breath. Asthma attacks often happen when there is inflammation in the lungs.

The study drug, AZD8154, has been developed as a treatment for asthma. AZD8154 was designed to stop several molecules that cause inflammation in the lungs. AZD8154 has already been studied in the form of a mist containing the drug, also known as a "nebulizer suspension". A nebulizer suspension is formed by a nebulizer, which is a device that turns a liquid into a mist. The researchers wanted to learn if a dry powder form of AZD8154 works similarly to the nebulizer suspension form of AZD8154.

In this study, the researchers compared how much AZD8154 got into the blood of healthy participants when inhaled in 2 different ways:

- As a nebulizer suspension
- As a dry powder through an inhaler

What was the purpose of this study?

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

- Did inhaling AZD8154 in different ways affect how much AZD8154 got into the participants' blood?
- 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 to find out if AZD8154 helps improve the health of people with asthma.

What treatments did the participants take?

In this study, the participants were planned to take the following treatments:

- AZD8154 as a nebulizer suspension
- AZD8154 as a dry powder through an inhaler
- A placebo

A placebo looks like a drug but does not have any medicine in it. The placebo looked the same as the AZD8154 dry powder. Researchers use a placebo to help make sure any of the effects they see in the participants who take the drug are actually caused by the drug.

It was planned for the participants to take all 3 treatments in a different order, with a 2-week wait between each treatment.

A computer program was used to randomly choose the order in which the participants were assigned to take 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.

This was an "open-label" study. This means the participants, researchers, study doctors and other study staff knew what each participant was taking.

The chart below shows the treatments the researchers planned to study.

	AZD8154 nebulizer suspension	AZD8154 dry powder	Placebo
	10 participants were planned to take all 3 treatments in different orders		
	As a nebulizer suspension	As a dry powder through an inhaler	As a dry powder through an inhaler
	• 1 dose for each treatment • At least a 2-week break before the next treatment		

What happened during this study?

It was planned for each participant to be in the study for about 13 weeks, but the study was stopped after just under 7 weeks. The study started in July 2020 and ended in September 2020.

The study was stopped early because of unexpected safety results in a different study that looked at how the dry powder form of AZD8154 worked in animals. Although the researchers did not think that the dry powder AZD8154 was a risk for the participants in this study, the animal safety results needed more research before this study could continue.

Before the participants took study treatment, they visited their study site once. At this visit, the study doctors made sure the participants could join the study.

The doctors also:

- did a physical exam and asked about the participants' medications, medical problems, and smoking history
- took urine and blood samples
- checked the participants' heart health by measuring blood pressure and pulse, and by using an electrocardiogram, also called an ECG
- checked the participants' lung health by measuring how much air they could breathe in and out, the speed of their breath, and the number of breaths they took every minute

The study doctors also did some of these tests and measurements at later visits throughout the study.

While the participants were taking study treatment, it was planned that they would visit their study site 4 times. But, since the study was stopped early, they had fewer visits. At each visit, the participants stayed overnight at their study site for 5 days.

It was planned that there would be at least 2 weeks between each visit. This part of the study was planned to last for about 8 weeks in total.

At these visits, the study doctors:

- gave the participants 1 dose of study treatment
- checked the participants' lung health and measured the amount of air they could breathe out
- asked the participants about their symptoms and taste
- monitored the participants' cough

After the participants had finished taking study treatment, they visited their study site for 1 last visit. This visit happened within about 1 week of their final treatment. At this visit, the study doctors checked the health of the participants.

What were the results of this 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 changes. The websites listed at the end of this summary may have more information about the study results.

Because the study was stopped early, none of the participants took all of their treatments. Each participant took only 1 of the 3 treatments that were planned.

Did inhaling AZD8154 in different ways affect how much AZD8154 got into the participants' blood?

Overall, a similar amount of AZD8154 got into the participants' blood when they inhaled AZD8154 in different ways.

To answer this question, the researchers took blood samples from all the participants. The researchers took blood samples before and after the participants got AZD8154 or the placebo, and measured how much AZD8154 was in the participants' blood. But the number of participants who took each study treatment was too small for the researchers to know if inhaling AZD8154 in different ways affected exactly how much AZD8154 got into the participants' blood.

What medical problems happened during this study?

The medical problems that the participants had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities.

The medical problems participants have during clinical studies that the study doctors think might be related to the study drug are called "adverse reactions".

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care. None of the participants had serious adverse reactions.

The adverse reactions that happen in a 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 other information about adverse reactions or other medical problems that happened during this study.

How has this study helped patients and researchers?

This study helped researchers learn more about how AZD8154 acts in the blood of healthy participants when inhaled in 2 different ways.

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 AZD8154 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 more information about the study results is available, it can also be found here.

- www.clinicaltrials.gov Once you are on the website, type **"NCT04480879"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home and Search"**, then type **"2019-004331-23"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D8900C00005"** into the search box, and click **"Find a Study"**.

Full Study Title: A Randomised, 3-Period, Single-dose, Open-label Crossover Study to Evaluate the Systemic Exposure of AZD8154 While Administered via Inhalation Using a Nebuliser Formulation and a Monodose Dry Powder Inhaler (DPI) Formulation in Healthy Subjects

AstraZeneca AB Protocol Number: D8900C00005

National Clinical Trials Number: NCT04480879

EudraCT Number: 2019-004331-23

AstraZeneca AB sponsored this study and has its headquarters at 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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