AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Abediterol

Study Title: A study to learn how much abediterol gets into the blood in healthy participants when taken in different ways

Thank you!

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

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 the study?

The researchers asked for the help of healthy men. The participants in this study were 20 to 45 years old when they joined.

The study included 25 participants, all in Germany.

Why was the research needed?

Researchers are looking for a different way to treat asthma and chronic obstructive pulmonary disease, also called COPD. 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 condition that causes the airways to narrow, swell, and create extra mucus. People with asthma may have symptoms such as coughing, wheezing, and difficulty breathing. There are treatments that can help control asthma symptoms, but these may not fully control asthma for some people.

COPD is a long-lasting inflammation of the lungs that blocks the airways and makes it difficult to breathe. It also causes shortness of breath.

Asthma and COPD treatments can be taken as dry powder through an inhaler. They can also be taken using a nebulizer. A nebulizer machine turns a liquid form of the treatment into a mist. This mist is slowly breathed in using a mask or mouthpiece.

The study drug, abediterol, is an inhaled treatment. Abediterol works by relaxing the airways in the breathing tubes to allow more air into the lungs. Researchers think this will make it easier for people with asthma or COPD to breathe.

In this study, the researchers wanted to find out about how much abediterol got into the participants' blood when it was taken through 2 different nebulizers or a dry powder inhaler.

What was the purpose of this study?

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

- How much abediterol got in 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 abediterol can help improve the health of people with asthma or COPD.

What treatments did the participants take?

All of the participants in this study took abediterol. They all took abediterol through 2 different nebulizers or a dry powder inhaler. The doses of abediterol were measured in micrograms, also known as µg.

The chart below shows the 4 different treatment groups that were planned.

Group	Treatment taken
1	2.4 µg of abediterol through nebulizer 1
2	4.8 µg of abediterol through nebulizer 1
3	2.4 µg of abediterol through nebulizer 2
4	2.5 µg of abediterol through a dry powder inhaler

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

A computer program was used to randomly choose the order of 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.

In this study, it was planned that the participants would take abediterol each of the 4 different ways one after the other. But, this did not happen because the researchers ended the study early.

What happened during the study?

The study started in January 2020 and ended in April 2020.

Before the participants took study treatment, they visited their study site 1 time. This happened about 4 weeks before the participants took abediterol. At this visit, the study doctors made sure that the participants could join the study. The study doctors:

- did a physical exam and asked about the participants' medications and any medical problems they were having
- checked the participants' lung health and measured the amount of air they could breathe out
- checked the participants' heart health using an electrocardiogram, also called an ECG
- took blood and urine samples
- showed the participants how to use their dry powder inhaler and nebulizers

The study doctors also did these tests and measurements throughout the study.

While the participants were taking study treatment, they stayed at the study site for 4 days. On day 2, they took their study treatment. Then, they had some blood tests on days 2 through to 4.

This happened a total of 4 times. At each stay, they took the study treatment in a different way.

There was a 2-week break between each stay.

After the participants took their last study treatment, they visited their study site 1 time up to 2 weeks later. At this visit, the study doctors checked the health of the participants.

It was planned for each participant to be in the study for 12 weeks, but the study sponsor made the decision to end the study early. This meant that not every participant had been in the study for 12 weeks.

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 changes.

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

There was 1 participant who did not get any of the study treatments. So, the results below include information for 24 out of 25 participants.

How much abediterol got in the participants' blood?

In the study, the researchers had planned to measure and compare how much abediterol got in the participants' blood when it was taken through 2 different nebulizers, or the dry powder inhaler.

The study sponsor made the decision to end the study early. Because there was a small number of participants when the study was ended, there was not enough information for the researchers to answer this question.

What medical problems happened during the study?

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.

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.

Did any adverse reactions happen during this study?

There were 4.2% of participants who had adverse reactions during this study. This was 1 out of 24 participants. This adverse reaction was shaking.

None of the participants had serious adverse reactions.

None of the participants stopped taking study treatment due to adverse reactions.

How has this study helped patients and researchers?

This study was planned to help researchers learn more about how much abediterol gets in the blood of healthy participants when it was taken through 2 different nebulizers, or the dry powder inhaler.

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 abediterol 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 **"NCT04199598"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6541C00001"** into the search box, and click **"Find a Study"**.

Full Study Title: An Open-label, Single-center, Randomized, 4-period, Single-dose, Crossover Study to Assess the Relative Bioavailability of Abediterol Inhaled via Two Different Nebulisers and via Dry Powder Inhaler in Healthy Subjects

AstraZeneca Protocol Number: D6541C00001

National Clinical Trials number: NCT04199598

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 and their families 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.

CISCRP | One Liberty Square, Suite 1100 • Boston, MA 02109 | 1-877-MED-HERO | www.ciscrp.org

Version 1.0 2021_02_12