

Clinical trial results



Research Sponsor: AstraZeneca AB

Drug Studied: abediterol

National Clinical Trial #: NCT02777827

Protocol #: D6540C00002

Study Date: June 2016 to November 2016

Short Study Title: A study in participants with asthma to learn more about how abediterol acts in the body and if the participants taking it have medical problems

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for the drug abediterol. This drug is being developed to treat asthma. You and all of the other participants helped researchers learn how abediterol affects the body and acts in the body, how much of abediterol reaches the blood, and if abediterol causes medical problems.

AstraZeneca AB, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

What has happened since my study ended?

Your study started in June 2016 and ended in November 2016. The study included 30 participants at 4 study sites in Germany. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Before a new drug can be approved, research must be done to show that it is safe and effective. The first step in studying a new drug is to test it in healthy people or in people without any serious health problems. The next step is to do research studies in people with health problems, also known as participants.

The study drug, abediterol, is being developed to treat asthma. Asthma is a lung disease that can cause coughing, wheezing, chest tightness, and difficulty breathing. Researchers wanted to know:

- How did abediterol affect the body?
- How did abediterol act in the body?
- How much of abediterol reached the blood?
- What medical problems did participants have after getting abediterol?

What kind of study was this?

Your study was a “double-blind” study. This means that neither the study staff nor the participants knew what treatment each participant got. Some studies are done this way because knowing what treatment each participant is getting can affect the results of the study. This way, the results are looked at fairly.

In this study, all participants got inhaler treatments of abediterol and a placebo. A placebo looks like the study drug but contains no real medicine in it. Researchers use placebos in studies to compare the results for participants who get study drugs with the results for participants who get no medicine at all. There were 5 inhaler treatments of abediterol and 1 inhaler treatment of placebo in this study.

Your study included 30 men and women with asthma who were 32 to 71 years old.

What happened during the study?

You and other participants were in the study for up to 15 weeks. One participant did not follow the treatment visit schedule and was only present for 3 of the 6 treatment periods. This participant did not complete the study.

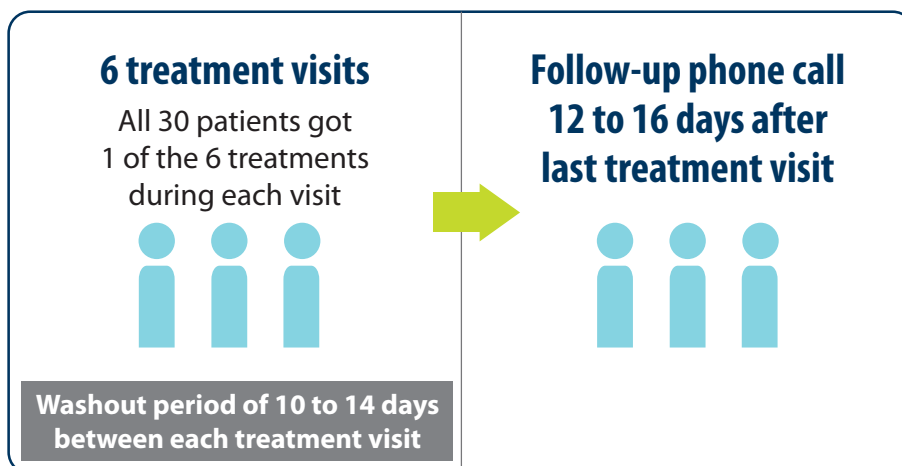
Before the study started, researchers did tests to check your health and asked you questions to make sure you could join the study. Researchers did a physical examination, which included checking your height, weight, and body temperature. Researchers tested samples of your urine and blood to check your overall health, and they did an electrocardiogram, or ECG, to check your heart health. Researchers also asked about your medical history, how you were feeling, and what medicines you were taking.

In this study, participants got 2 different types of inhalers. The first type of inhaler delivers medicine in a dry powder form. The second type of inhaler delivers medicine in a spray form.

The abediterol treatments were given in micrograms, or μg . This is a widely accepted scientific unit of measurement. You and all of the other participants got all 6 inhaler treatments listed below in random order.

- 0.156 μg of abediterol in Inhaler 1
- 2.5 μg of abediterol in Inhaler 1
- 0.05 μg of abediterol in Inhaler 2
- 0.156 μg of abediterol in Inhaler 2
- 2.5 μg of abediterol in Inhaler 2
- Placebo

The figure below shows how the study was done.



In between the 6 treatment visits, there were “washout periods” of 10 to 14 days. During the washout periods, participants were not allowed to take certain drugs. This helped get rid of any effects from previous treatments.

During the study, researchers did tests to check the health of the participants.

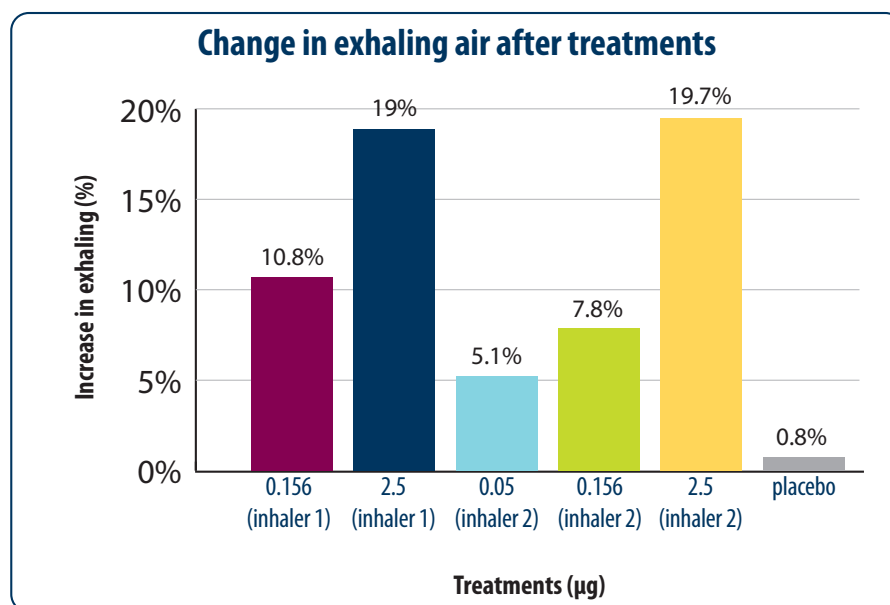
At the end of the study, researchers called all of the participants 12 to 16 days after their last visit. During this follow-up phone call, researchers asked participants how they were feeling.

What were the study results?

Below is a summary of the results of some of the questions the researchers asked during this study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for participants. Further clinical studies with abediterol are currently planned.

How did abediterol affect the body?

Researchers wanted to know how the study drug affected the body. So they measured how much air participants could exhale after getting the treatments. The figure below shows these amounts after participants got all 6 treatments:



Researchers found that the increase in the amount of air that participants could exhale was largest after they got the 2.5 µg treatments in both types of inhaler. This increase was similar between these 2 inhalers.

How did abediterol act in the body?

Researchers wanted to know how the study drug acted in the body. They also wanted to compare the results between the 2 inhalers. So for both inhalers, they measured:

- The average amount of abediterol in the blood
- The highest amount of abediterol in the blood
- How long it took for abediterol to reach its highest amount in the blood

Researchers found that the 0.05 µg and 0.156 µg treatments were too low to be measured in the blood for both types of inhalers.

Researchers found that the average amount of abediterol in the blood was largest when participants got the 2.5 µg inhaler treatments in both types of inhaler. These average amounts were similar between these 2 inhalers.

Researchers found that the highest amount of abediterol in the blood was largest when participants got the 2.5 µg inhaler treatments in both types of inhaler. These highest amounts were similar between these 2 inhalers.

It took a similar amount of time for abediterol to reach its highest amount in the blood when participants got the 2.5 µg treatments in both types of inhaler. It took about 30 minutes for this to happen for both of these inhaler treatments.

How much of abediterol reached the blood?

Researchers found that there was no significant difference in how much of the study drug reached the blood in participants who got the 2.5 µg treatments in both types of inhaler.

What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are studied, researchers keep track of all the medical problems that participants have during the study. These medical problems are called “adverse events”. They may or may not be caused by the study drug.

How many participants developed medical problems during the study?

The table below shows how many participants developed medical problems during the study. Overall, 23 out of 30 participants (76.7%) had at least 1 medical problem during the study. None of the participants stopped taking the study drug because of a medical problem.

Two participants (6.7%) had at least 1 medical problem that researchers thought was possibly related to the study drug. These possibly related medical problems were abnormal lung test results, difficulty breathing, dizziness, and headache.

	0.156 µg of abediterol in inhaler 1 (Out of 29 participants)	2.5 µg of abediterol in inhaler 1 (Out of 29 participants)	0.05 µg of abediterol in inhaler 2 (Out of 30 participants)	0.156 µg of abediterol in inhaler 2 (Out of 30 participants)	2.5 µg of abediterol in inhaler 2 (Out of 30 participants)	Placebo (Out of 29 participants)
How many participants developed medical problems?	7 (24.1%)	10 (34.5%)	7 (23.3%)	6 (20.0%)	7 (23.3%)	12 (41.4%)

How many participants developed serious medical problems?

A medical problem is considered serious when it is life-threatening, causes lasting problems, or needs hospitalization. There were no deaths in this study, and no participants developed serious medical problems. No safety concerns were raised during this study.

What were the most common medical problems in the study that were not considered serious?

The table below shows all of the medical problems that were not considered serious that happened in at least 5% of participants.

Medical problems that were not considered serious	0.156 µg of abediterol in inhaler 1 (Out of 29 participants)	2.5 µg of abediterol in inhaler 1 (Out of 29 participants)	0.05 µg of abediterol in inhaler 2 (Out of 30 participants)	0.156 µg of abediterol in inhaler 2 (Out of 30 participants)	2.5 µg of abediterol in inhaler 2 (Out of 30 participants)	Placebo (Out of 29 participants)
Headache	3 (10.3%)	2 (6.9%)	3 (10.0%)	3 (10.0%)	3 (10.0%)	6 (20.7%)
Toothache	0 (0.0%)	0 (0.0%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Common cold	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.7%)	0 (0.0%)	2 (6.9%)
Joint pain	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.9%)

Where can I learn more about the study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/NCT02777827.

Official study title: A Randomised, Double-Blind, Double Dummy, Placebo-Controlled, Multi Centre, Six-Way, Crossover Study to Assess the Pharmacodynamics, Pharmacokinetics, and Safety of Abediterol Single Dose, Given by Dry Powder Inhaler (DPI) or Pressurised Metered-Dose Inhaler (pMDI), in Participants with Asthma on Inhaled Corticosteroids.

AstraZeneca AB is the sponsor of this study and has its headquarters in Södertälje, Sweden.

The phone number for the AstraZeneca Information Center is 1-877-240-9479.

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest act is one which is performed anonymously, giving when you do not know whether you will get direct personal benefit.

This is the act that you have performed by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health. Thank you for the gift of your participation in clinical research.



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 trials, nor is it involved in conducting clinical trials.

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