

**Research Sponsor:** AstraZeneca AB

**Treatment studied:** Abediterol

**Study title:** A study to learn how abediterol acts in the blood of people with asthma who are already taking a steroid inhaler treatment, and if abediterol is safe to take

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## ***Thank you!***

Thank you to the participants who took part in the clinical trial for the study treatment abediterol.

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

If you participated in this 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 September 2017 and ended in October 2017.

The sponsor 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 asthma. Before a treatment can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

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

- How did abediterol act in the blood of the participants?
- 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 help find out if abediterol improves the health of people with asthma.

In this study, the researchers wanted to find out how an inhaler treatment of abediterol acts in the blood of participants with asthma. Asthma is a disease that can cause swelling in the lungs, which can make it difficult to breathe.

The participants in this study were already taking a steroid inhaler treatment. A steroid inhaler treatment can help reduce swelling in the body. Abediterol is an inhaler treatment that may help relax muscles in the lungs. The researchers in this study wanted to learn if an abediterol treatment taken with a steroid treatment could help improve breathing by relaxing the muscles in the lungs and reducing swelling.

## What kind of study was this?

This was a “single-blind” study. This means the researchers knew what the participants were taking, but the participants did not.

The participants in this study took either abediterol or a placebo through an inhaler. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the study treatment are actually caused by the study treatment.

A computer program was used to randomly choose the 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?

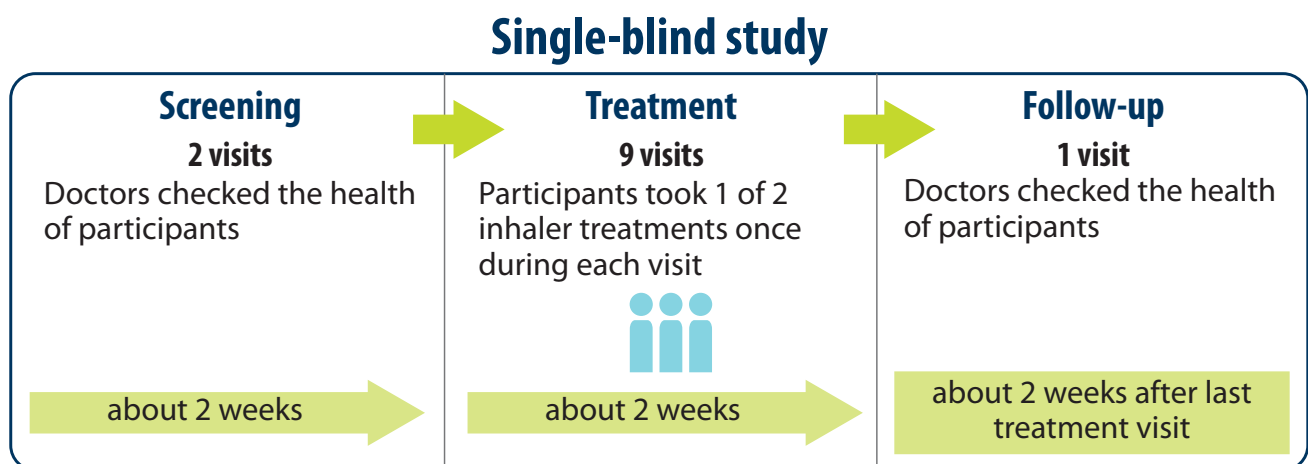
**Before the study started**, the doctors:

- did a physical examination
- checked the heart health of the participants using an electrocardiogram, also known as an ECG
- took blood and urine samples
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

**During the study**, the participants took either the abediterol inhaler treatment or the placebo inhaler treatment once a day for 9 days. Throughout the study, the participants also continued taking the steroid inhaler treatment they were already taking.

**At the end of the study**, the participants visited their study site 1 more time. During this visit, the doctors checked the health of the participants again and asked how they were feeling.

The figure 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. 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 abediterol act in the blood of the participants?

In general, the researchers found that more abediterol reached the blood of the participants on Day 9 compared to Day 1.

To answer this question, the researchers 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

In general, the researchers found that on Day 9:

- The average amount of abediterol in the blood was 90.2 picogram hours per milliliter, also known as h\*pg/mL. This amount was 26.5 h\*pg/mL on Day 1.
- The highest amount of abediterol in the blood was 8.1 picograms per milliliter, also known as pg/mL. This amount was 3.8 pg/mL on Day 1.

It took 15 to 30 minutes for abediterol to reach its highest amount in the blood.

### What medical problems did the participants have during the study?

The medical problems that the participants had in 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 that participants have during clinical studies that the doctors think might be related to the study treatment 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 treatment. A lot of research is needed to know whether a treatment causes an adverse reaction.

## How has this study helped patients and researchers?

This study helped researchers learn how abediterol acts in the blood of participants with asthma who are already taking a steroid inhaler treatment. It also helped researchers learn if abediterol 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. Always talk to a doctor before making any treatment changes.

Further clinical studies with abediterol are 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](http://www.clinicaltrials.gov). Once you are on the website, type “**NCT03273127**” into the search box and click “**Search**”.
- [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type “**D6540C00006**” into the search box, and click “**Find a Study**”.

**Full study title:** A Phase 1, Randomized, Single-Blind, Placebo-Controlled Study To Assess Pharmacokinetics, Safety and Tolerability Of Abediterol Administered Once Daily for 9 Days, In Patients with Asthma On Inhaled Corticosteroids

**AstraZeneca Protocol number:** D6540C00006

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 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 participants.



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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