Clinical Study Results

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Research Sponsor: Pearl Therapeutics, Inc., a member of the AstraZeneca Group

Treatment Studied: Albuterol sulfate pressurized inhalation suspension, also called AS MDI

Study Title: This study was done to learn how different doses of albuterol sulfate given in an inhaler worked and how safe it was in people with asthma

Thank you!

Thank you for taking part in the clinical study of the treatment AS MDI, also called albuterol sulfate pressurized inhalation suspension. You and all the participants helped researchers learn more about AS MDI to help people with asthma.

Pearl Therapeutics, Inc. sponsored this study and thinks it is important to share the results of the study with you and the public. An independent, non-profit organization called CISCRP helped prepare this summary of the study results for you. We hope it helps you understand and feel proud of your important role in medical research.

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?

You and the other participants were in the study for up to about 10 weeks. The study started in December 2017 and ended in March 2018. The study took place in the USA. It included 86 participants; 78 participants completed the study.

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 people with asthma. Before a treatment can be approved for people to take, researchers do clinical studies to find out how it works and how safe it is. In this study, the researchers wanted to find out if AS MDI works in a small number of participants with mild to moderate asthma. They also wanted to find out if the participants had any medical problems during the study.

Asthma is a condition that causes the airways to narrow. This makes it difficult to breathe. People with asthma can have wheezing, coughing, shortness of breath, and chest tightness. There is currently no cure for asthma, but there are treatments that can help with the symptoms.

Albuterol sulfate, also known as albuterol, is a standard treatment for asthma. It works by relaxing muscles in the breathing tubes to allow more air into the lungs. This makes it easier to breathe. Albuterol is given to asthma patients in an inhaler that delivers a specific amount of medication to the lungs. The inhaler is known as a metered dose inhaler. One of the current asthma treatments is called Proventil HFA, also known as Proventil. This treatment also contains albuterol. In this study, AS MDI contains a different formulation of albuterol compared to the current treatment.

In this study, the researchers wanted to find out how different doses of AS MDI work in people with asthma.

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

- How much air could the participants breathe out after taking AS MDI?
- What medical problems did participants have during the study?

To answer the questions in this study, researchers asked for the help of males and females who had asthma for at least 6 months and did not have any other lung condition or infection. The participants in this study were 13 to 64 years old.

What kind of study was this?

There were 2 parts in this study; both parts happened at the same time:

One part of this study was "double-blind". This means none of the participants, doctors or other study staff knew what treatment each participant took in this part. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. When the study ended, the research sponsor found out which treatment participants took so they could create a report of the study results.

In this part of the study the participants took AS MDI or placebo. 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 a treatment are actually caused by the treatment.

The other part of the study was "open-label". This means that the participants, doctors or other study staff knew what the participants were taking. In this part of the study the participants took the standard Proventil asthma treatment.

All of the participants took AS MDI, Proventil, and the placebo during the study. Doses were measured in micrograms, also called µg. At each visit, participants took 1 of the 5 treatments, then at the next study visit, switched treatment:

- Placebo
- AS MDI 90 µg
- AS MDI 180 µg
- Proventil 90 µg
- Proventil 180 µg

A computer program was used to randomly choose the order that 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?

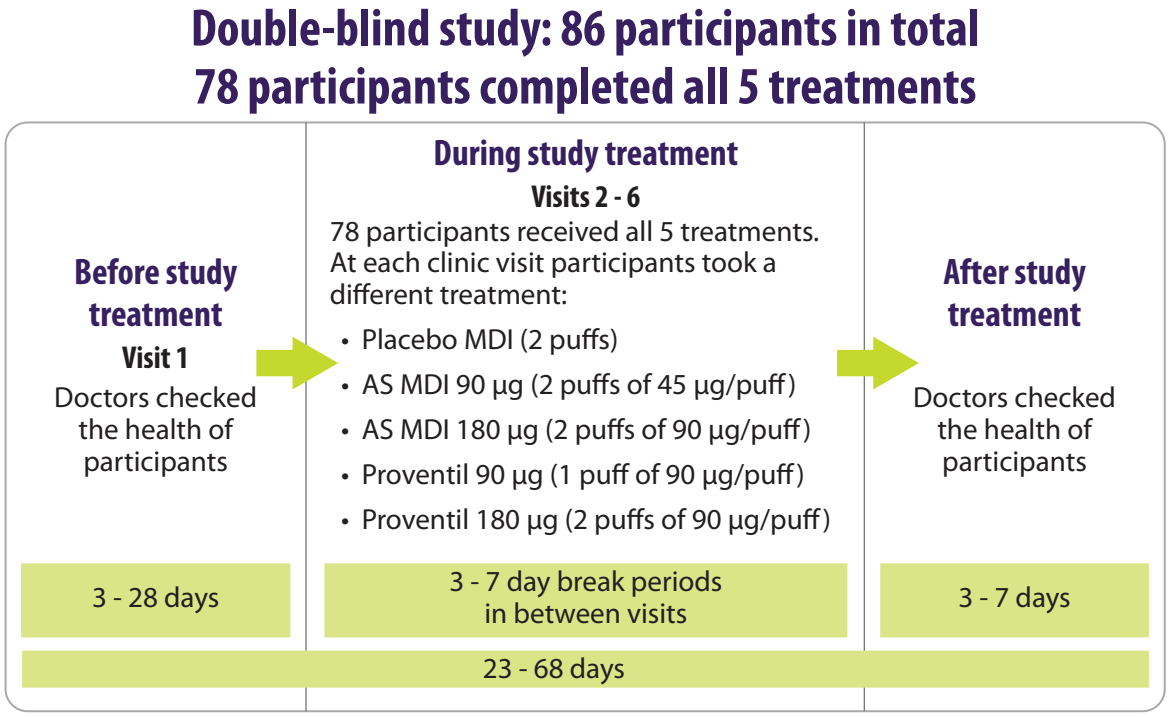
Before study treatment, the doctors checked your overall health to see if you could join the study. They asked about your medical history, how you were feeling and what medications you were taking. They took blood and urine samples from you. If the doctors found that you were able to join the study, they asked you to stop any treatments you were taking for asthma. This helped the doctors make sure any effects they saw during treatment were due to the treatment in this study.

During the study, you and the other participants visited your study site up to 5 times. At each visit, you took AS MDI, Proventil, or the placebo.

At each visit, the doctors or study staff measured the amount of air that you could breathe out before and after you took each treatment. The researchers wanted to see how the treatment affected your breathing.

After the study ended, the doctors called you to see how you 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. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of the summary. If a full report of the study results is available, it can also be found on these websites.

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.

How much air could the participants breathe out after taking AS MDI?

The researchers found that after taking either dose of AS MDI, the participants:

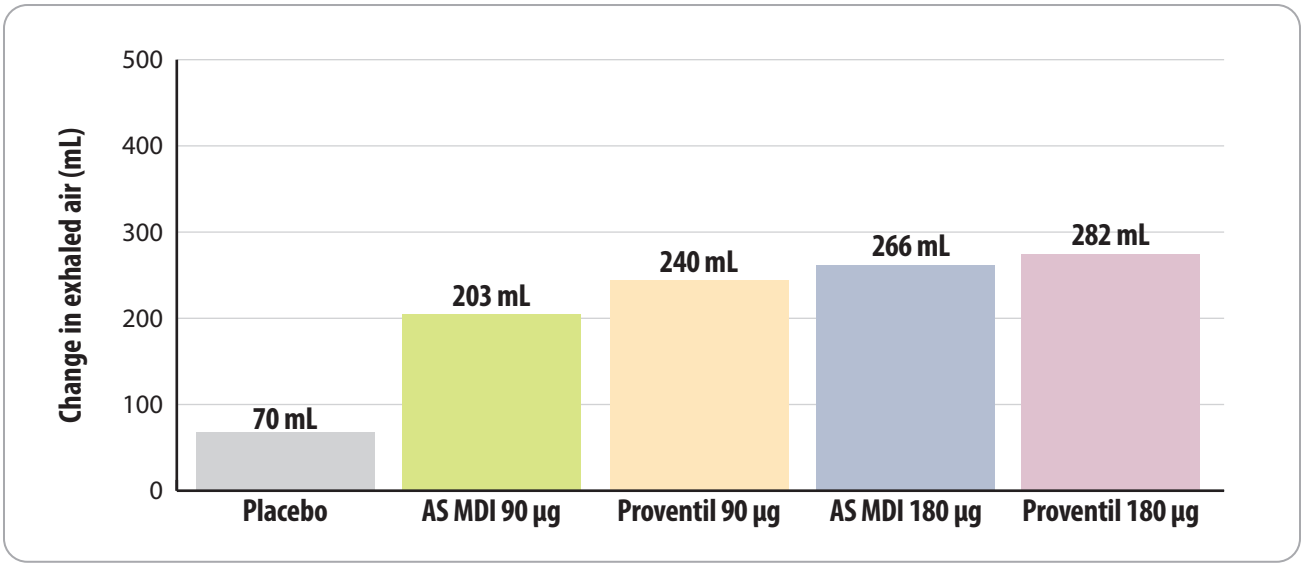
- breathed out more air compared to taking a placebo that contains no medicine
- breathed out about the same amount of air compared to taking the same dose of Proventil

To answer this question, the researchers compared how much air participants could breathe out before and 6 hours after taking each treatment. The researchers found that the participants who took:

- placebo could exhale 70 mL more air
- 90 µg of AS MDI could exhale 203 mL more air
- 90 µg of Proventil could exhale 240 mL more air
- 180 µg of AS MDI could exhale 266 mL more air
- 180 µg of Proventil could exhale 282 mL more air

The chart below shows these results.

Change in exhaled air



What medical problems did participants have?

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 treatment. 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 treatment. 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?

None of the participants had a serious adverse reaction.

How many participants had adverse reactions?

None of the participants had an adverse reaction.

How has this study helped patients and researchers?

This study helped researchers learn how much air the participants with asthma could breathe out after taking different doses of AS MDI.

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 AS MDI are planned.

Where can I learn more about the 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. Once you are on the website, type **"NCT03364608"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6930C00001"** into the search box and click **"Find a Study"**.

Full study title: A randomized, double-blind, single dose, placebo-controlled, 5-period, 5-treatment, crossover, multi-center, dose-ranging study to compare PT007 to placebo MDI and open-label Proventil® HFA in adult and adolescent subjects with mild to moderate asthma (ANTORA).

National Clinical Trial number: NCT03364608

AstraZeneca Protocol number: D6930C00001 (PT007001)

Pearl Therapeutics, Inc, a member of the AstraZeneca Group, sponsored this study and has its headquarters in Morristown, USA.

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.

CISCRP
THE CENTER FOR INFORMATION & STUDY ON CLINICAL RESEARCH PARTICIPATION

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 patients for clinical studies, nor is it involved in conducting clinical studies.

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