Clinical Study Results

Pearl™
A member of the AstraZeneca Group

Research sponsor: Pearl Therapeutics, Inc.

Drugs studied: Budesonide, Glycopyrronium, and Formoterol Fumarate

Short study title: A study to learn how an inhaler treatment with 3 combined drugs acts in the body of healthy adults

Thank you!

Thank you to the participants who took part in this clinical trial for the study drugs budesonide, glycopyrronium, and formoterol fumarate.

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. 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?

The participants were in the study for up to about 6 weeks. But, the entire study took about 5 months to finish.

The study started in April 2017 and ended in September 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 chronic obstructive pulmonary disease, also known as COPD. Before a treatment can be approved for patients 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 how a 3-drug inhaler treatment and a 2-drug inhaler treatment acted in the body. The researchers also wanted to find out if the participants had any medical problems during the study.

In this study, the researchers studied 3 different treatments taken through an inhaler. One of the treatments was an inhaler treatment that had only glycopyrronium and formoterol fumarate. The other 2 treatments were different doses of an inhaler treatment that had budesonide, glycopyrronium, and formoterol fumarate. These 2 inhaler treatments are not yet approved in China for COPD patients to take.

The main question the researchers wanted to answer in this study was:

- How did the 3-drug treatment and the 2-drug treatment act in the body?

What kind of study was this?

This was a “double-blind” study. This means none of the participants, doctors, or other study staff knew what treatment each participant took.

All of the participants in the study took either the inhaler treatment that had only glycopyrronium and formoterol fumarate or 1 of the 2 inhaler treatments that had budesonide, glycopyrronium, and formoterol fumarate.

A computer program was used to randomly choose the treatment each participant took. 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 participants visited their study site 2 times so that the doctors could:

- check their health to make sure they could join the study
- take blood and urine samples
- check their heart health using an electrocardiogram, also known as an ECG

During the study, the participants visited their study site 2 more times. During the first of these 2 visits, the participants stayed at their study site for 7 days. On the first day, they took 1 of the 3 inhaler treatments once a day. For the next 6 days, they took their inhaler treatment twice a day.

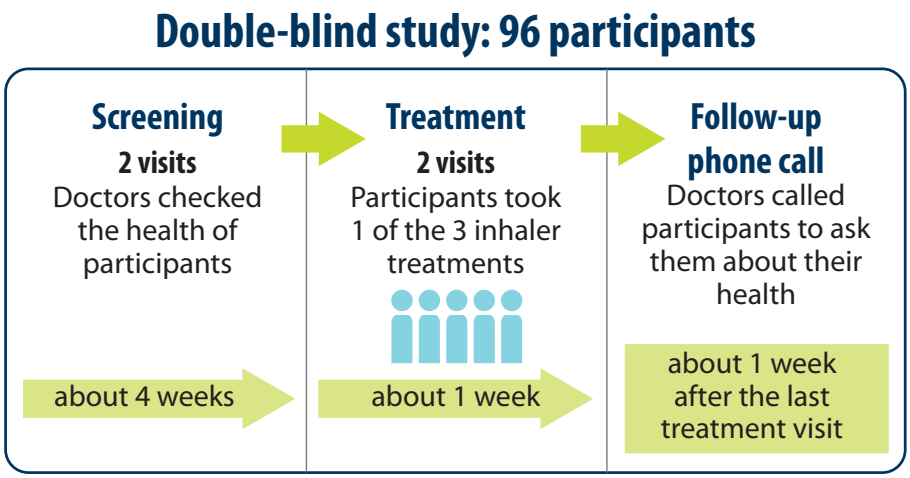
During these 7 days, the participants took 1 of the below treatments:

- the inhaler treatment that had a lower dose of budesonide, glycopyrronium, and formoterol fumarate
- the inhaler treatment that had a higher dose of budesonide, glycopyrronium, and formoterol fumarate
- the inhaler treatment that had only glycopyrronium and formoterol fumarate

After the 7-day visit ended, the participants stayed at the study site 1 more day to take 1 more dose of the inhaler treatment. The doctors also checked the health of the participants again.

About 1 week after this last visit, the doctors called the participants to ask them about their health.

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 individual 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 website listed at the end of this summary. If a full report of the study results is available, it can also be found on this website.

How did the 3-drug treatment and the 2-drug treatment act in the body?

The researchers wanted to find out how the 3-drug treatment and the 2-drug treatment acted in the body.

The researchers took blood samples from the participants at different times during the study. Then, the researchers measured:

- the average amount of the study drugs in the blood
- the highest amount of the study drugs in the blood
- how long it took for the study drugs to reach their highest amount in the blood

In general, the researchers found that after 7 days of treatment:

Budesonide

- The participants who took the higher dose of the 3-drug treatment had higher average and overall amounts of budesonide in their blood compared to the participants who took the lower dose of the 3-drug treatment.
- It took the same amount of time for budesonide to reach its highest amount in the blood for the participants in both of the 3-drug treatment groups.

Glycopyrronium

- The average and overall amounts of glycopyrronium in the blood were similar among all 3 treatment groups.
- It took the same amount of time for glycopyrronium to reach its highest amount in the blood among all 3 treatment groups.

Formoterol fumarate

- The average and overall amounts of formoterol fumarate in the blood were similar among all 3 treatment groups.
- It took the same amount of time for formoterol fumarate to reach its highest amount in the blood among all 3 treatment groups.

What medical problems did the participants have?

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

The adverse reactions that happened in this study are not in this summary because there was a small number of participants in the study. Leaving this information out helps protect their identities. The website listed at the end of this summary may have other information about medical problems that happened in this study.

How has this study helped patients and researchers?

This study helped researchers learn how a 3-drug treatment and the 2-drug treatment acted in the body.

The results presented here are for a single study. 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.

Further clinical studies with the inhaler combination of budesonide, glycopyrronium, and formoterol fumarate are planned.

Where can I learn more about the study?

You can find more information about this study on the website listed below. If a full report of the study results is available, it also can be found there.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03075267"** into the search box and click **"Search"**.

The full title of your study is: A Phase I, Randomized, Double-Blind, Parallel-Group Study to Assess the Pharmacokinetics and Safety of Two Doses of PT010 and a Single Dose of PT003 in Healthy Chinese Adult Subjects Following a Single Administration and After Chronic Administration for 7 Days

The protocol number of your study is: PT010010 (D5980C00005)

Pearl Therapeutics, Inc., a member of the AstraZeneca Group, sponsored this study and has its headquarters at 280 Headquarters Plaza, Morristown, NJ 07960.

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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