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 budesonide, glycopyrronium, and formoterol fumarate act in the body when combined in an inhaler

Thank you!

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

Pearl Therapeutics, Inc. sponsored this study and thinks it is important to share the results 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 this study and have questions about the results, please speak with the doctor or staff at your study site.

What is happening with this study now?

The participants were in this study for about 6 weeks. But, the entire study took about 4 months to finish.

This study started in August 2017 and ended in December 2017. The sponsor reviewed the data collected when this study ended and created a report of the results. This is a summary of that report.

Why was the research needed?

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. Researchers are looking for a better way to treat chronic obstructive pulmonary disease, also known as COPD. COPD is a disease that can cause swelling in the lungs, which can make it difficult to breathe.

In this study, the researchers wanted to find out if the participants had any medical problems during the study. They also wanted to learn how budesonide, glycopyrronium, and formoterol fumarate act in the body when combined in an inhaler.

This information is important to know before other studies can be done that help find out if the study treatment can improve the health of people with COPD.

Budesonide, glycopyrronium, and formoterol fumarate are drugs that are already approved to treat COPD. But, these 3 drugs are not yet approved to take together in an inhaler treatment.

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

- How did the inhaler treatment of the 3 combined drugs act in the body?

What kind of study was this?

This was an “open-label” study. This means the researchers and the participants knew what the participants were taking.

What happened during this study?

Before this study started, the doctors:

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

Once the participants joined this study, it could take a few weeks before they went back to the study site to start the study treatment.

During this study, the participants visited their study site 5 times.

They took the study treatment:

- once on Day 1
- twice each day from Day 2 through Day 7
- once on Day 8

All of the participants took the same dose of the study treatment.

At the end of this study, the doctors called the participants and asked how they were feeling.

What were the study results?

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 the 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 inhaler treatment of the 3 combined drugs act in the body?

In general, the 3 combined drugs acted similarly in the body.

To answer this question, the researchers measured:

- the average amount of the 3 drugs in the blood
- the highest amount of the 3 drugs in the blood
- how long it took for each drug to reach its highest amount in the blood

They measured these amounts on Day 1 and Day 8, and then compared these results.

After 1 week of treatment, the researchers found that:

- The average amount of the 3 drugs in the blood of the participants was higher on Day 8 compared to Day 1.
- The highest amount of the 3 drugs in the blood of the participants was similar on Day 8 compared to Day 1.
- It took slightly longer for each of the 3 drugs to reach their highest amount in the blood of the participants on Day 8 compared to Day 1.

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 very small number of participants, 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 budesonide, glycopyrronium, and formoterol fumarate act in the body when combined in an inhaler.

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 budesonide, glycopyrronium, and formoterol fumarate combined in an inhaler are planned.

Where can I learn more about this 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 can also be found there.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03250182"** into the search box and click **"Search"**.

Full study title: A Study to Assess the Pharmacokinetics and Safety of PT010 in Subjects with Moderate to Severe COPD Following Single and Repeat Dose Administration

Protocol number: PT010018

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.