Clinical Study Results

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

Drugs Studied: Glycopyrronium and formoterol fumarate, also called GFF

Study Title: A study to see if GFF affects blood flow in the hearts in participants with chronic obstructive pulmonary disease

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Thank you!

Thank you to the participants who took part in the clinical study for the study drugs glycopyrronium and formoterol fumarate, also called PT003 or GFF.

Pearl Therapeutics, Inc. sponsored this study and thinks it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their 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?

Each participant was in the study for up to 12 weeks. But, the entire study lasted about 1.5 years. This is because the participants joined the study at different times. The study started in December 2016 and ended in June 2018. The researchers planned to include 40 participants in the study. The study was stopped early because not enough people took part. The study only included 4 participants.

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 chronic obstructive pulmonary disease, also called COPD. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works. In this study, the researchers wanted to find out if GFF changes how blood flows through the heart in participants with COPD. They also wanted to find out if the participants had any medical problems during the study.

COPD is a long-term condition that causes the airways to narrow. This can make it difficult to breathe. COPD can also reduce the amount of blood that moves through the heart. There are treatments for COPD to help people breathe more easily, but these treatments do not work well for everyone with moderate to very severe COPD.

GFF is used to treat COPD. It works by relaxing muscles in the airways to allow more air into the lungs. This makes it easier to breathe. Researchers think that GFF might also increase blood flow through the heart.

GFF is taken through an inhaler that brings a specific amount of GFF to the lungs. The inhaler is known as a metered dose inhaler, also called MDI.

The researchers in this study wanted to find out if GFF affected how blood flows through the heart in participants with moderate or severe COPD.

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

- Did blood flow through the heart differently after the participants took GFF?
- What medical problems did the participants have during the study?

To answer the questions in this study, researchers asked for the help of men and women with moderate or severe COPD. The participants in this study smoked at least 10 pack-years, which means they had smoked an average of at least 1 pack of cigarettes a day for 10 years.

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. 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.

This study had 2 parts. All 4 participants were in both parts of the study. A computer program was used to randomly choose the order that each participant took each study 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. By the end of the study, all the participants had taken both study treatments.

In Part 1, the participants took either GFF 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 a study drug are actually caused by the study drug.

The participants took 2 puffs of the inhaler twice a day for 1 week. Doses of GFF were measured in micrograms, also called µg. The GFF inhaler had 14.4 µg of glycopyrronium and 9.6 µg of formoterol fumarate.

In Part 2, the participants took either GFF or a placebo through an inhaler. In this part of the study, the participants took the treatment that they did not take in Part 1. They took 2 puffs of the inhaler twice a day for 1 week.

What happened during the study?

Before the study, the participants visited the study site 2 times. At these visits, the doctors checked the participants’ overall health and lungs to make sure they could join the study. If participants were able to join the study, the doctors may have asked them to stop taking certain medicines. This helped make sure any effects the researchers saw in the participants were due to the treatment in the study.

At the first visit, the doctors took a picture of each participant’s heart using magnetic resonance imaging, also called MRI. The doctors used the MRI to measure the amount of blood in different parts of the heart.

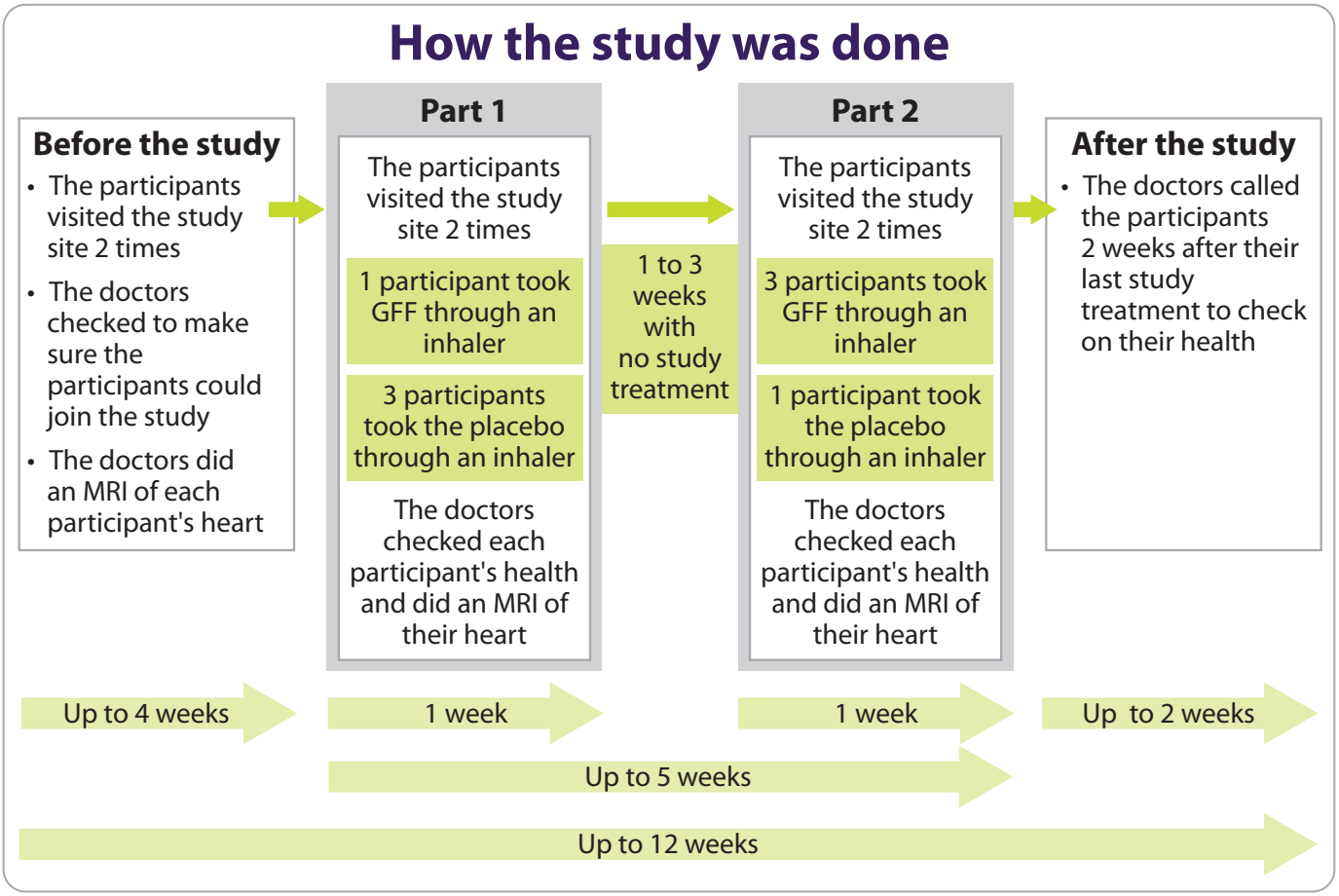
During the study, the participants visited the study site 2 times in Part 1, and 2 times in Part 2. At the first visit, the participants got their inhaler, and the doctors checked the participants' health. At the second visit, the doctors did an MRI to check the amount of blood in different parts of the participants' hearts. At this visit, the doctors also checked the participants' health.

After Part 1, the participants waited 1 to 3 weeks before starting Part 2. This was done so that all of the study treatment could completely leave their bodies.

All the participants took part in both parts of the study, but they took GFF and the placebo in a different order.

Two weeks after participants took the last study treatment, the doctors called the participants to see how they were feeling.

The chart below shows how the study was done.



What were the results of the study?

Because the researchers were not able to include as many participants as they planned, they ended the study early. So, the researchers were not able to get the information they needed to answer their questions about GFF in this study.

What medical problems did participants have during the study?

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

During this study, there were no adverse reactions.

How has this study helped patients and researchers?

Because this study ended early, there was not enough information to help the researchers find out if GFF affected how the participants’ blood flowed through the heart.

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.

Further clinical studies with GFF are not currently 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 **"NCT02685293"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"PT003017"** into the search box and click **"Find a Study"**.

Full study title: A Randomized, Phase IIIb, Two-period, Double-blind, Two-treatment, Chronic-dosing (7 Days), Single-center Crossover Study to Evaluate the Treatment Effect of PT003 on Cardiovascular Hemodynamics in Subjects With Moderate to Severe Chronic Obstructive Pulmonary Disease, Compared With Placebo

National Clinical Trial number: NCT02685293

AstraZeneca Protocol number: PT003017

Pearl Therapeutics, Inc., sponsored this study and has its headquarters in Morristown, NJ, 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 (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.

CISCRP
One Liberty Square, Suite 1100 • Boston, MA 02109
1-877-MED-HERO • www.ciscrp.org