AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca

Drug Studied: Budesonide, glycopyrronium, and formoterol fumarate

Study Title: A study to learn how much of a combination of budesonide, glycopyrronium, and formoterol fumarate reaches the lungs in participants with chronic obstructive pulmonary disease

Protocol Number: D5980C00020

Thank you!

Thank you to the participants who took part in the clinical study for the study drug combination of budesonide, glycopyrronium, and formoterol fumarate. AstraZeneca sponsored this study and thinks it is important to share the results. An independent non-profit organisation called CISCRP helped prepare this summary of the study results.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

Who took part in this study?

The researchers asked for the help of men and women with chronic obstructive pulmonary disease. The participants in this study were 46 to 78 years old when they joined.

The study included 18 participants in the United Kingdom.

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 who have chronic obstructive pulmonary disease, also called COPD. Before a drug or a combination of drugs can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

COPD is a long-term condition caused by damage to and narrowing of the airways. This can lead to symptoms such as difficulty breathing, coughing, and phlegm.

There are treatments that help people manage their COPD symptoms. But, these treatments may not work for some people. They may also cause medical problems for some people.

The study drugs, budesonide, glycopyrronium, and formoterol fumarate, are each inhaled treatments that doctors currently use to help people who have COPD manage their symptoms. But, these study drugs are not available combined in the same inhaler. Researchers think that combined inhaled treatments of these study drugs may help people who have COPD to better manage their symptoms.

In this study, the researchers wanted to learn how budesonide, glycopyrronium, and formoterol fumarate reach the lungs when they are delivered through 1 inhaler in participants who have COPD. This information may help researchers find out which combined treatments to give to future study participants.

What was the purpose of this study?

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

- How much of the combined inhaled study drugs reached the lungs?
- What medical problems happened during the study?

The answers to these questions are important to know so that researchers can learn more about how combined doses of budesonide, glycopyrronium, and formoterol fumarate act in the body of people who have COPD.

What treatments did the participants take?

The researchers in this study wanted to learn how much of a combined inhaled treatment of budesonide, glycopyrronium, and formoterol fumarate reached the lungs in participants with COPD. They also wanted to compare these results between participants with moderate COPD and participants with severe or very severe COPD. COPD is called moderate, severe, or very severe depending on how much it affects a person's breathing.

In this study, there were 2 groups of participants. Both groups took budesonide, glycopyrronium, and formoterol fumarate through an inhaler. The groups were based on how severe the participants' COPD was:

- 10 participants had moderate COPD
- 8 participants had severe or very severe COPD

Each group took the same doses of the study drugs during the study. The doses were measured in micrograms, also called µg. Each participant took 1 dose of the study drug.

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

The chart below shows the treatment the participants took.

	18 participants
	• Budesonide, glycopyrronium, and formoterol fumarate combined into a single treatment
	• 320 µg of budesonide • 14.4 µg of glycopyrronium • 9.6 µg of formoterol fumarate
	• Through an inhaler
	• 1 dose during the study

What happened during this study?

The study started in May 2019 and ended in March 2020. Each participant was in the study for about 6 weeks, but the entire study took 10 months to finish.

The chart below shows what happened during the study.

Before the participants took the study drugs

1 visit

The study doctors checked to make sure the participants could join the study.

The study doctors:

- did a physical examination and checked the participants' vital signs
- took urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- checked the participants' lung health
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

Up to 1 month

While the participants took the study drugs

1 visit

The participants stayed overnight at their study site. On the second day, they took 1 dose of budesonide, glycopyrronium, and formoterol fumarate combined.

2 days

After the participants took the study drugs

The study doctors called the participants to ask them how they were feeling.

About 2 weeks after treatment

What were the results of this 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 changes.

The researchers were not able to use the results of 1 participant who had moderate COPD. This was because the participant did not use their inhaler correctly. So, the below results are for 17 of the 18 participants.

The websites listed at the end of this summary may have more information about the study results.

How much of the combined inhaled study drugs reached the lungs?

To answer this question, the study doctors "radiolabeled" the study drugs before the participants inhaled them. This means that the study doctors added a safe amount of a radioactive substance to the study drugs. Right after the participants inhaled the study drugs, they held their breath for no more than 10 seconds, and then released it. Then, the study doctors scanned the participants' lungs. In these scans, the radiolabeled substance helped them "see" the study drugs in the lungs and other parts of the body.

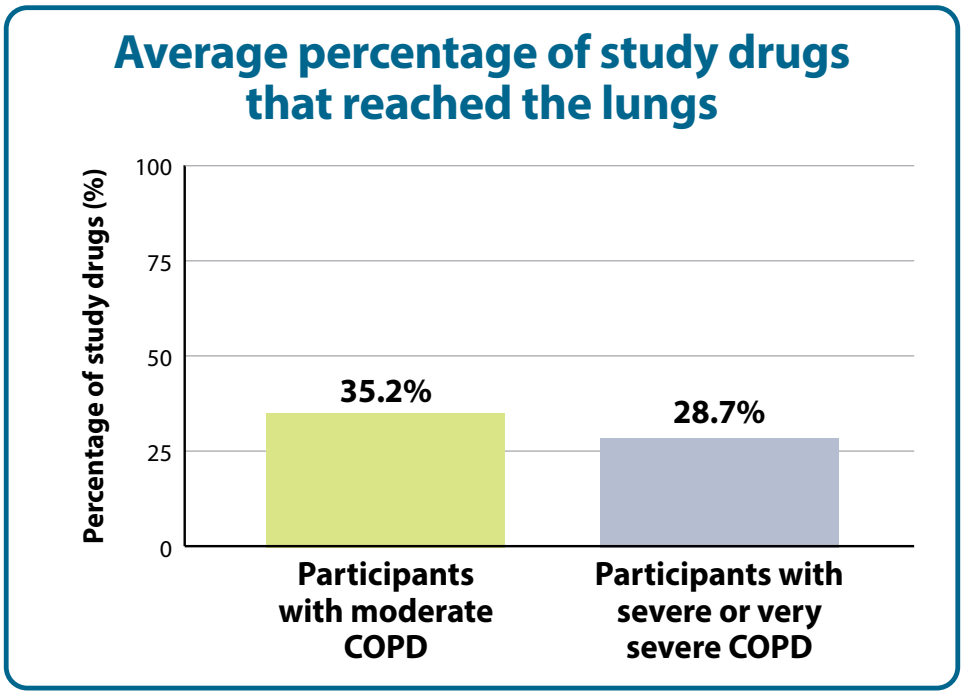
The study doctors calculated the average percentage of the study drugs that reached the lungs in the overall group of participants. They also compared these amounts in the participants with moderate COPD to those with severe or very severe COPD.

The researchers found that the percentage of the study drugs that reached the lungs was similar in both treatment groups.

Overall, the researchers found that:

- 32.1% of the study drugs reached the lungs in the overall group of participants.
- 35.2% of the study drugs reached the lungs in the participants with moderate COPD.
- 28.7% of the study drugs reached the lungs in the participants with severe or very severe COPD.

The figure below shows these results.



What medical problems happened during the study?

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.

Adverse reactions may or may not be caused by a 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 other medical problems that happened during this study.

Did any adverse reactions happen during this study?

None of the participants had adverse reactions during this study.

None of the participants had serious adverse reactions during this study.

None of the participants died during this study.

How has this study helped patients and researchers?

This study helped researchers learn how much of a combination of budesonide, glycopyrronium, and formoterol fumarate reaches the lungs in participants with COPD.

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 1 study. Other studies may provide new information or different results.

Further clinical studies with budesonide, glycopyrronium, and formoterol fumarate combined are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT03906045"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5980C00020"** into the search box, and click **"Find a Study"**.

Full Study Title: A Phase I, Single-Dose, Gamma Scintigraphy Study to Assess the Pulmonary Deposition of Technetium-99m Radiolabeled Budesonide, Glycopyrronium and Formoterol Fumarate MDI Following a Maximal Breath-Hold of up to 10 seconds in Patients with Moderate to Severe/Very Severe Chronic Obstructive Pulmonary Disease

AstraZeneca Protocol Number: D5980C00020

AstraZeneca sponsored this study and has its headquarters at 1800 Concord Pike in Wilmington, Delaware

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you!

Participants in clinical studies 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 patients.

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

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Version 1.0 2021_05_21