Clinical Study Results

Research Sponsor: AstraZeneca Gothenburg

Drugs Studied: Budesonide, glycopyrronium and formoterol fumarate, also called BGF

Study Title: A study to learn how much BGF got into the lungs of healthy participants.

Thank you!

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

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 study started in September 2018 and ended in October 2018. The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

The study included 10 participants from the United Kingdom.

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.

COPD is a long-term condition that causes the airways to narrow or damages the tiny air sacs in the lungs. This makes it difficult to breathe. There are treatments for COPD, but these treatments do not work for all patients. Budesonide, glycopyrronium and formoterol fumarate work to open up the airways. Each of these is used on its own or in pairs to treat the symptoms of COPD.

This study used a new form of BGF in an inhaler. The BGF had a small amount of radioactive substance added to it so that it could be seen in images of the lungs.

In this study, the researchers wanted to find out how much BGF got into the lungs in a small number of healthy participants. This would help them learn how BGF works before giving it to patients with COPD.

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

- How much BGF got into the participants' lungs?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done that help find out if BGF improves the health of people with COPD.

The researchers asked for the help of healthy male participants.

What kind of study was this?

This was an "open-label" study. This means the researchers and the participant knew what the participant was taking.

All the participants took BGF through an inhaler.

What happened during the study?

Before the participants took BGF, the doctors checked their overall health to make sure that they could join the study. This included:

- taking blood and urine samples
- lung function tests
- heart health tests using an electrocardiogram, also called an ECG

The participants also learned how to use the inhaler to take BGF.

During the study, the participants visited the study site 2 times. They stayed overnight each time. At each visit:

- the participants took 2 inhaler puffs of BGF
- the doctors checked the participants' health
- the doctors took scans of the participants' lungs

After taking BGF at each visit, the participants were asked to hold their breath. In 1 part of the study, they held their breath for 3 seconds. In the other part of the study, they held their breath for 10 seconds. The order that each participant completed each part was chosen randomly. By the end of the study, each participant had completed both parts.

The participants waited about 7 days in between taking study treatment in each part. This was done so that all of the BGF could leave their bodies before they took it again.

After the participants took BGF, the doctors called the participants 7 to 14 days after their last dose of BGF to check on their health.

What were the results of the study?

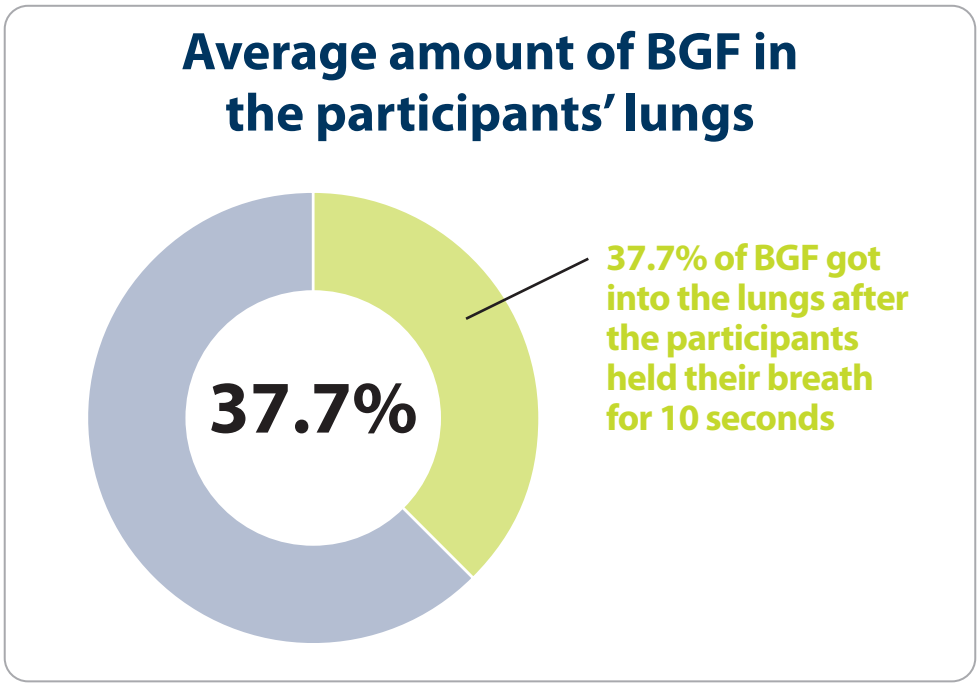
This is a summary of the main results from this study overall. The results each participant had might be different and are not in this summary.

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 change.

The website listed at the end of this summary may have a full report of the study results.

How much BGF got into the participants' lungs?

On average, 37.7% of the BGF got into the participants' lungs. This was measured after the participants used the inhaler and then held their breath for 10 seconds. Participants held their breath to make sure that as much BGF as possible stayed in the lungs after they breathed out again. The doctors used a scan called "gamma scintigraphy imaging" to measure how much BGF got into the lungs.



It is important to know the study was designed to get the most accurate results when the participants held their breath for 10 seconds. But, the doctors also measured how much BGF got into lungs after the participants held their breath for 3 seconds. On average, 34.5% of the BGF from the inhaler got into the participants' lungs after they held their breath for 3 seconds.

What medical problems did participants have 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.

The adverse reactions that happen in a study may or may not be caused by the study treatment. A lot of research is needed to know whether a study 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 serious adverse reactions during this study.

How many participants had adverse reactions?

None of the participants had adverse reactions during this study.

How has this study helped patients and researchers?

This study helped researchers learn how much BGF got into the lungs of healthy male participants.

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 BGF are planned.

Where can I learn more about this 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 **"NCT03740373"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5980C00007"** into the search box and click **"Find a Study"**.

Full Trial Title: A Phase I, Randomized, Two-Period, Single-Dose, Single-Centre, Crossover Gamma Scintigraphy Study to Assess the Pulmonary Deposition of Technetium-99m Radiolabeled Budesonide, Glycopyrronium and Formoterol Fumarate MDI, Following 3 s and 10 s Breath-Hold, in Healthy Male Subjects

National Clinical Trials number: NCT03740373

AstraZeneca Protocol Number: D5980C00007

AstraZeneca Gothenburg, sponsored this study and has its headquarters in Mölndal, Sweden.

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.