AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Treatments Studied:
- Budesonide and formoterol fumarate inhalation aerosol
- Budesonide and formoterol fumarate dry powder inhaler

Study Purpose: This study was done to learn how budesonide and formoterol fumarate inhalation aerosol works in participants with chronic obstructive pulmonary disease

Protocol Number: D5980C00023

Thank you!

Thank you for taking part in the clinical study for these 2 study treatments:

- budesonide and formoterol fumarate inhalation aerosol, also known as budesonide and formoterol fumarate metered dose inhaler or "BFF MDI"
- budesonide and formoterol fumarate dry powder inhaler, also known as "BFF DPI"

You and all of the participants helped researchers learn more about BFF MDI and BFF DPI to help people with long-standing, severe chronic obstructive pulmonary disease, also called COPD.

AstraZeneca AB sponsored this study and believes 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 for you. 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 study doctor or staff at your study site.

Overview of this study

Why was the research needed?

Researchers are looking for a better way to treat participants with long-standing, severe COPD. Before a treatment can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

What treatments did the participants take?

The participants in this study took both:

- budesonide and formoterol fumarate through a metered dose inhaler, also known as BFF MDI
- budesonide and formoterol fumarate through a dry powder inhaler, also known as BFF DPI

What were the results of this study?

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

- **Did BFF MDI affect how much air the participants could breathe out compared with BFF DPI?**

  Overall, BFF delivered through either an MDI or a DPI increased the amount of air the participants could breathe out. The researchers found that the MDI and DPI worked equally well, and did not find a difference between the MDI and DPI in the amount of air the participants could breathe out.

- **What medical problems did the participants have during this study?**

  None of the participants had medical problems that the study doctors thought might be related to the study treatments during the study.

More details about the results of this study are included later in this summary.

Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on these websites.

Who took part in this study?

The researchers asked for the help of men and women with long-standing, severe COPD. The participants in this study were 50 to 76 years old when they joined. Before joining this study, the participants:

- were taking at least 2 long-term treatments for COPD
- had lung health tests showing that their COPD was severe
- were current or former smokers with at least a 10-year history of smoking often

The study included 35 participants in Germany.

Why was the research needed?

Researchers are looking for a better way to treat long-standing, severe COPD. Before a treatment can be approved for people 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 if BFF MDI worked better than BFF DPI in a small number of participants with long-standing, severe COPD.

COPD is a lung disease that causes blocked airways and inflammation, making it hard for air to flow in and out of the lungs. It also causes shortness of breath. COPD gets worse over time. Most people who have COPD are current or former smokers.

BFF DPI is an approved treatment that is commonly used by people with COPD. It works by expanding the airways in the lungs and reducing inflammation. This can help people with COPD breathe more easily.

In this study, BFF could be taken through 2 different types of inhalers: an MDI or a DPI. They are both devices that deliver a specific amount of a drug for a patient to breathe in. They are different in how patients take them and how patients breathe in when using the device.

In this study, the researchers wanted to find out how much air the participants could breathe out after a week of taking BFF delivered through either an MDI or DPI. They also wanted to find out if the participants had any medical problems during the study.

What was the purpose of this study?

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

- Did BFF MDI affect how much air the participants could breathe out compared with BFF DPI?
- 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 to find out if BFF delivered through an MDI helps improve the health of people with long-standing, severe COPD, compared with a DPI.

What treatments did the participants take?

In this study, all of the participants took BFF MDI and BFF DPI.

There were 2 groups of participants. This study was a "crossover" study. A crossover study means that all of the participants took the same 2 treatments, but in a different order. The participants took each treatment twice a day for 1 week.

In between taking each study treatment, the participants had a "wash-out" period where they did not take any BFF to let it clear from their system.

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

A computer program was used to randomly choose the treatment each participant took first. 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.

The chart below shows the treatments the researchers planned to study.

	Group 1	Group 2
	18 participants	17 participants
	• BFF MDI through an inhaler • BFF DPI through an inhaler	• BFF DPI through an inhaler • BFF MDI through an inhaler
	BFF **MDI** for 1 week, taken 2 times a day **THEN** A 2-week wash-out period **THEN** BFF **DPI** for 1 week, taken 2 times a day	BFF **DPI** for 1 week, taken 2 times a day **THEN** A 2-week wash-out period **THEN** BFF **MDI** for 1 week, taken 2 times a day

What happened during this study?

The participants were in the study for up to 9 weeks. But, the entire study took 16 months to finish.

The study started in September 2019 and ended in December 2020. The study was paused due to COVID-19 between March 2020 and September 2020.

The chart below shows what happened during the study.

Before the participants took study treatment

1 visit

The study doctors:

- checked the health of the participants to make sure they could join the study
- did a physical exam and asked about the participants' medications and any medical problems
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- checked the participants' lung health and measured the amount of air they could breathe out
- checked how well the participants were able to do their usual daily activities

2 weeks

While the participants took study treatment

5 visits

The study doctors:

- did a physical exam and asked about the participants' medications and any medical problems
- checked the participants' lung health and measured the amount of air they could breathe out

The participants:

- took the study treatment

1 month

After the participants took study treatment

1 visit

The study doctors:

- did a physical exam and asked about the participants' medications and any medical problems

2 weeks

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. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. When a full report of the study results is available, it can also be found on these websites.

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 results below are for the 30 out of 35 participants who completed both study treatments.

Did BFF MDI affect how much air the participants could breathe out compared with BFF DPI?

Overall, BFF delivered through either an MDI or a DPI increased the amount of air the participants could breathe out. The researchers found that the MDI and DPI worked equally well, and did not find a difference between the MDI and DPI in the amount of air the participants could breathe out.

To answer this question, the study doctors measured the amount of air the participants breathed out in 1 second. This was measured in liters, also called L. The study doctors measured the average amount of air breathed out after the participants took each of the study treatments for 1 week. Then, they compared these measurements to the average amount of air breathed out before the participants took the study treatments and calculated the average change. They compared the results from when the participants took BFF MDI with the results from when they took BFF DPI.

After 1 week of treatment, the amount of air that the participants breathed out in 1 second:

- increased by 0.26L with BFF MDI
- increased by 0.27L with BFF DPI

Overall, the difference between the 2 treatments was too small for the researchers to know if BFF MDI affected how much air the participants could breathe out compared with BFF DPI.

What medical problems happened during this 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 treatments. 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.

These adverse reactions 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the study treatments.

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.

Did any adverse reactions happen during this study?

None of the participants in this study had adverse reactions.

How has this study helped patients and researchers?

This study helped researchers learn more about how 2 different types of BFF inhalers work in participants with long-standing severe 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 one study. Other studies may provide new information or different results.

Further clinical studies with BFF MDI are planned.

Where can I learn more about this study?

You can find more information about this study on the websites listed below. If more information about the study results is available, it can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type **"NCT04078126"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2019-001801-26"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5980C00023"** into the search box and click **"Find a Study"**.

Full Study Title: A Randomized, Open-Label, Two Period Crossover, Chronic Dosing, 1-Week, Pilot Study to Assess the Efficacy and Safety of Budesonide and Formoterol Fumarate Inhalation Aerosol Administered with a Spacer Compared with Symbicort® Turbuhaler® in Subjects with Severe to Very Severe Chronic Obstructive Pulmonary Disease and Low Peak Inspiratory Flow

AstraZeneca Protocol Number: D5980C00023

National Clinical Trials Number: NCT04078126

EudraCT Number: 2019-001801-26

AstraZeneca AB sponsored this study and has its headquarters in Södertälje, 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 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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