Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca

Drug Studied: Aclidinium bromide + formoterol fumarate

Study Title: A study to learn how much aclidinium bromide and formoterol fumarate was in the blood when taken together, and how safe they were in Chinese patients with COPD

Thank you!

Thank you to the participants who took part in the clinical study for the study drug combination of aclidinium bromide and formoterol fumarate, also called AB/FF. You and all of the participants helped researchers learn more about using AB/FF to help people with chronic obstructive pulmonary disease, also called COPD.

AstraZeneca 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 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 doctor or staff at your study site.

What is happening with the study now?

The participants were in the study for up to about 5 weeks. But, the entire study took about 6 months to finish. The study started in December 2017 and ended in June 2018.

The study included 20 participants in China.

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 patients with COPD. Before a drug can be approved for patients to take, researchers do clinical studies to figure out how it works and how safe it is.

COPD is a long-term condition that causes the airways to narrow. This can cause medical problems like coughing, lung infection, and difficulty breathing.

In this study, the researchers wanted to find out how much AB/FF and 2 AB "metabolites" were in the blood in a small number of participants with COPD. Metabolites are substances the body creates to break down a drug and remove it from the blood and body through fluids, such as urine or sweat. When a person takes AB/FF, their body breaks down AB into 2 different metabolites.

At the time of this study, AB/FF was being used to treat patients who have COPD in some countries, but not in China. So, the researchers wanted to learn more about how much of AB/FF and the 2 AB metabolites were in the blood of Chinese patients. The researchers also wanted to find out if the participants had any medical problems during the study.

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

- How much of AB/FF and the AB metabolites were in the blood?
- What medical problems did the participants have during the study?

To answer the questions in this study, the researchers asked for the help of Chinese men and women with COPD. The participants in this study were 41 to 67 years old.

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.

All of the participants took AB/FF through an inhaler.

What happened during the study?

Before the participants took the study drug, the doctors checked to make sure they could join the study. The doctors:

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

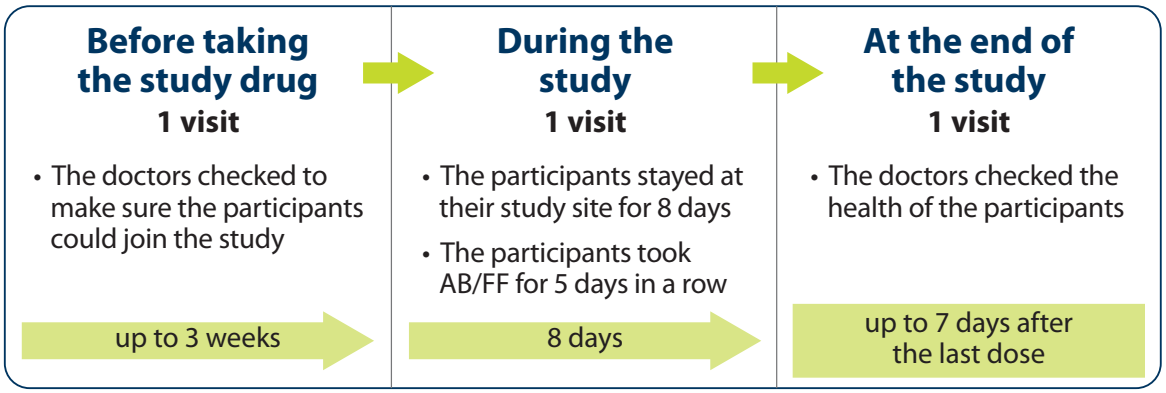
During the study, the participants visited their study site 1 time and stayed at the site for 8 days. On 5 of these days, the participants took AB/FF through an inhaler. The participants took AB/FF 2 times a day for 4 days in a row. On Day 5, they took AB/FF 1 time.

The AB/FF doses were measured in micrograms, also called µg. Each AB dose was 400 µg, and each FF dose was 12 µg.

Throughout the study, the doctors took blood and urine samples. They also checked the participants' overall health.

At the end of the study, the participants visited their study site 1 more time so the doctors could check their health and ask them how they were feeling.

The chart below shows how the study was done.



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. A full list of the questions the researchers wanted to answer can be found on the websites listed at the end of this summary. If 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.

How much of AB/FF and the AB metabolites were in the blood?

To answer this question, the doctors tested participants' blood throughout the study and focused on measurements for AB, the 2 AB metabolites, and FF. They studied the results for these measurements on the first and fifth days that the participants took AB/FF.

In this study, the researchers focused on the following measurements for AB, the 2 AB metabolites, and FF:

- how long it took for them to reach their highest amounts in the blood
- the average amounts in the blood
- how long it took for half of the amounts to leave the blood after the last dose

On the first day the participants took AB/FF:

- It took about 0.1 hours for AB to reach its highest amount in the blood.
- It took about 1.8 hours for the first AB metabolite to reach its highest amount in the blood.
- It took about 3.0 hours for the second AB metabolite to reach its highest amount in the blood.
- It took about 1.0 hour for FF to reach its highest amount in the blood.

On the fifth day the participants took AB/FF:

- It took about 0.1 hours for AB to reach its highest amount in the blood.
- It took about 0.5 hours for the first AB metabolite to reach its highest amount in the blood.
- It took about 3.0 hours for the second AB metabolite to reach its highest amount in the blood.
- The average amounts of both AB and the first AB metabolite in the blood were about twice as high as they were on the first day. These amounts were higher compared to the second AB metabolite.
- It took about 19.4 hours for half of AB to leave the blood. It took a similar amount of time for half of the 2 AB metabolites to leave the blood.
- It took about 0.1 hours for FF to reach its highest amount in the blood.
- The average amount of FF in the blood was about 1.5 times as high as it was on the first day.
- It took about 14.1 hours for half of FF to leave the blood.

What medical problems did the 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 drug. 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 drug. A lot of research is needed to know whether a drug 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 the study.

None of the participants died because of serious adverse reactions during the study.

How many participants had adverse reactions?

There were 15.0% of participants who had adverse reactions during the study. This was 3 out of 20 participants.

None of the participants stopped taking the study drug because of adverse reactions they had during the study.

What adverse reactions did the participants have?

The most common adverse reaction during the study was having protein in the urine.

The table below shows the adverse reactions that happened during the study. There was 1 participant who had 2 adverse reactions.

Adverse reactions

	AB/FF (out of 20 participants)
Having protein in urine	15.0% (3)
Having blood in urine	5.0% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about how AB/FF acts in the blood.

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 AB/FF are not planned. However, there was 1 other AB/FF study ongoing in China when this summary was written.

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 "**NCT03276078**" into the search box, and click "**Search**".
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6572C00001"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase IIa, Open-Label, Repeat-Dose Clinical Trial to Evaluate the Pharmacokinetics, Safety and Tolerability of Aclidinium Bromide/Formoterol Fumarate Fixed Dose Combination Administered Twice-Daily by Inhalation in Chinese Patients With Moderate to Severe Chronic Obstructive Pulmonary Disease

AstraZeneca Protocol Number: D6572C00001

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!

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.