Clinical Study Results

Research Sponsor: AstraZeneca AB

Drugs Studied: Budesonide and albuterol sulfate

Study Title: A study to learn how budesonide and albuterol sulfate taken together act in healthy participants, and about the safety of these drugs taken together

Thank you!

Thank you to the participants who took part in the clinical study for the study drugs budesonide and albuterol sulfate. AstraZeneca AB 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.

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 January 2019 and ended in May 2019. The study included 91 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 patients who have asthma. 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.

Asthma is a condition that causes a person's airways to narrow, swell, and create extra mucus. This can lead to several symptoms, including chest pain, coughing, and difficulty breathing. Currently, there is no cure for asthma.

Budesonide and albuterol sulfate are 2 inhaler treatments that doctors currently use to help asthma patients control their symptoms. Both of these drugs are used on their own, but they are not available combined in the same inhaler. Researchers think that taking the 2 drugs combined in the same inhaler may help asthma patients better control their asthma.

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

- Did budesonide and albuterol sulfate act differently in the body when taken together?
- 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 budesonide and albuterol sulfate taken together improve the health of asthma patients.

The researchers asked for the help of healthy men and women. The participants in this study were 19 to 55 years old when they joined.

What kind of study was this?

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

There were 3 treatments in this study, which were all taken through an inhaler. All of the participants took all 3 treatments, but in a different order:

- inhaler treatment of budesonide only
- inhaler treatment of albuterol sulfate only
- combined inhaler treatment of budesonide and albuterol sulfate

The treatment doses were measured in micrograms, also called µg.

A computer program was used to randomly choose the order in which the participants took each treatment. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

Before the participants took treatment, they visited their study site at least 1 time over the course of about 4 weeks. At this visit, the study doctors checked to make sure the participants could join the study. The study 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
- explained to the participants how to take their inhaler treatments during the study

During the study, the participants visited their study site 3 times over the course of about 3 weeks. The participants stayed at their study site for 2 days during each of these visits.

At each visit, the participants took 2 puffs of 1 of the below inhaler treatments:

- inhaled dose of 80 µg of budesonide
- inhaled dose of 90 µg of albuterol sulfate
- combined inhaled doses of 80 µg of budesonide and 90 µg of albuterol sulfate

There was a "washout period" of about 1 week in between each visit. During this time, the participants did not take any study treatment. This was done so that each treatment could be "washed out" of their bodies before they took the next treatment.

After the participants got their last treatment, they visited their study site 1 time about 1 week after they got their final study treatment. At this visit, the study doctors checked the participants' health and asked them how they were feeling.

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

Some of the participants left the study before the researchers could measure and compare the study results. These participants left because of a medical problem or because they did not follow the study guidelines. So, the below results are for only some of the 91 participants. The number of participants included for each measurement are presented below.

Did budesonide and albuterol sulfate act differently in the body when taken together?

No. Overall, the researchers found that there was little difference in how the drugs acted in the body when taken together compared to when taken alone.

To answer this question, the doctors measured the amount of budesonide and albuterol sulfate in the blood at different times for the first 24 hours after participants took their treatment.

The researchers studied 3 different measurements:

- The amount of the drugs in the blood during the 24 hours after treatment. This was measured in picogram hours per milliliter, also called pg*h/mL.
- The amount of the drugs in the blood until the amounts became too low for the researchers to measure. This was measured in pg*h/mL.
- The highest amount of the drugs in the blood during the 24 hours after treatment. This was measured in picograms per milliliter, also called pg/mL.

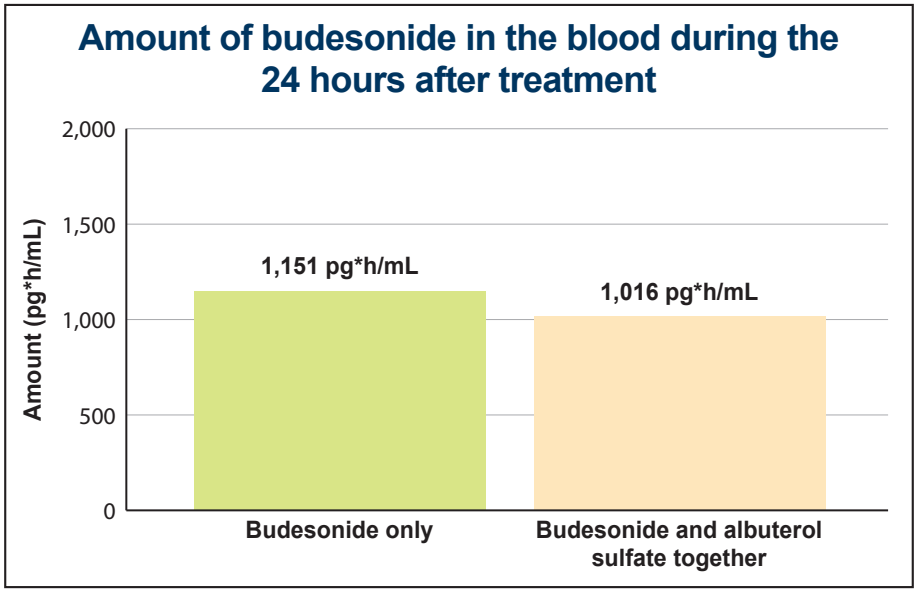
Overall, the researchers found there was little difference in these measurements for the 3 treatments throughout the study. The results of these measurements are listed below.

Amount of the drugs in the blood during the 24 hours after treatment

Budesonide:

- The amount of budesonide in the blood when participants took budesonide only was 1,151 pg*h/mL. These results include 89 of the 91 participants.
- The amount of budesonide in the blood when participants took budesonide and albuterol sulfate together was 1,016 pg*h/mL. These results include 85 of the 91 participants.

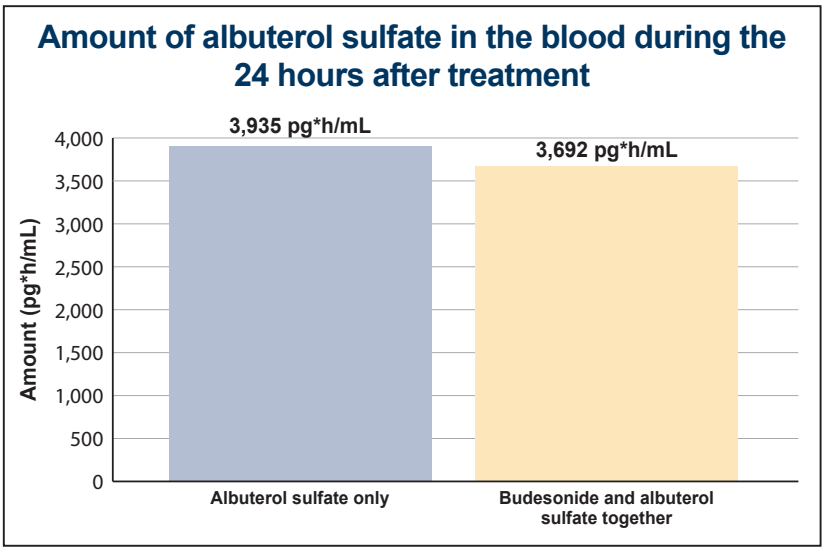
The figure below shows these results.



Albuterol sulfate:

- The amount of albuterol sulfate in the blood when participants took albuterol sulfate only was 3,935 pg*h/mL. These results include 89 of the 91 participants.
- The amount of albuterol sulfate in the blood when participants took budesonide and albuterol sulfate together was 3,692 pg*h/mL. These results include 87 of the 91 participants.

The figure below shows these results.

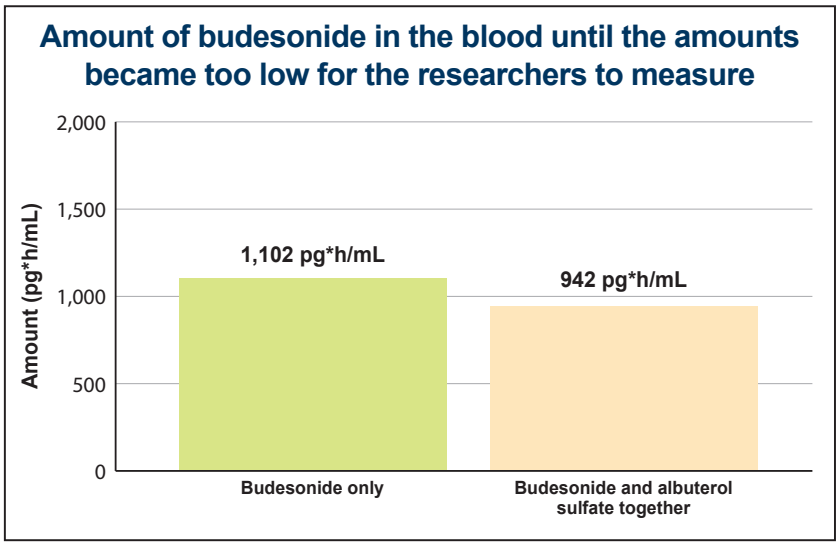


Amount of the drugs in the blood until the amounts became too low for the researchers to measure

Budesonide:

- The amount of budesonide in the blood when the participants took budesonide only was 1,102 pg*h/mL. These results include 89 of the 91 participants.
- The amount of budesonide in the blood when the participants took budesonide and albuterol sulfate together was 942 pg*h/mL. These results include 89 of the 91 participants.

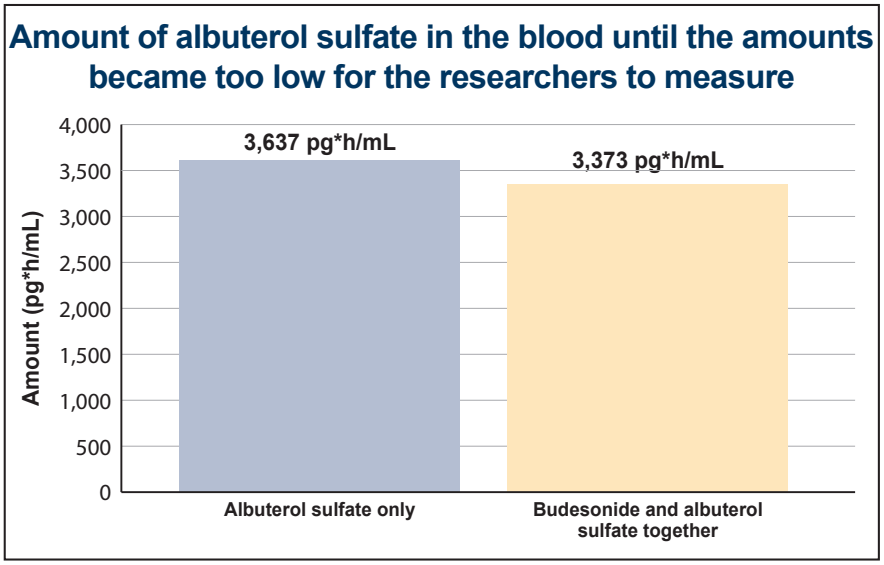
The figure below shows these results.



Albuterol sulfate:

- The amount of albuterol sulfate in the blood when the participants took albuterol sulfate only was 3,637 pg*h/mL. These results include 90 of the 91 participants.
- The amount of albuterol sulfate in the blood when the participants took budesonide and albuterol sulfate together was 3,373 pg*h/mL. These results include 89 of the 91 participants.

The figure below shows these results.

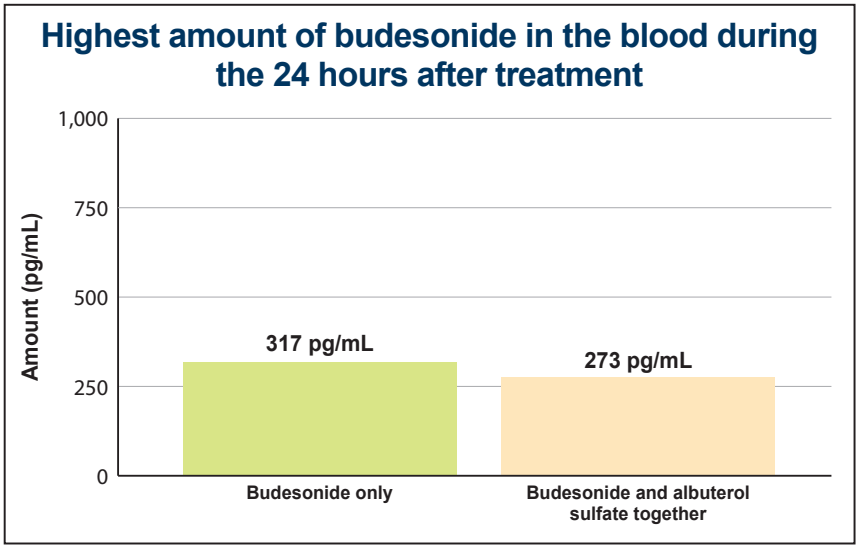


Highest amount of the drugs in the blood during the 24 hours after treatment

Budesonide:

- The highest amount of budesonide in the blood when the participants took budesonide only was 317 pg/mL. These results include 89 of the 91 participants.
- The highest amount of budesonide in the blood when the participants took budesonide and albuterol sulfate together was 273 pg/mL. These results include 88 of the 91 participants.

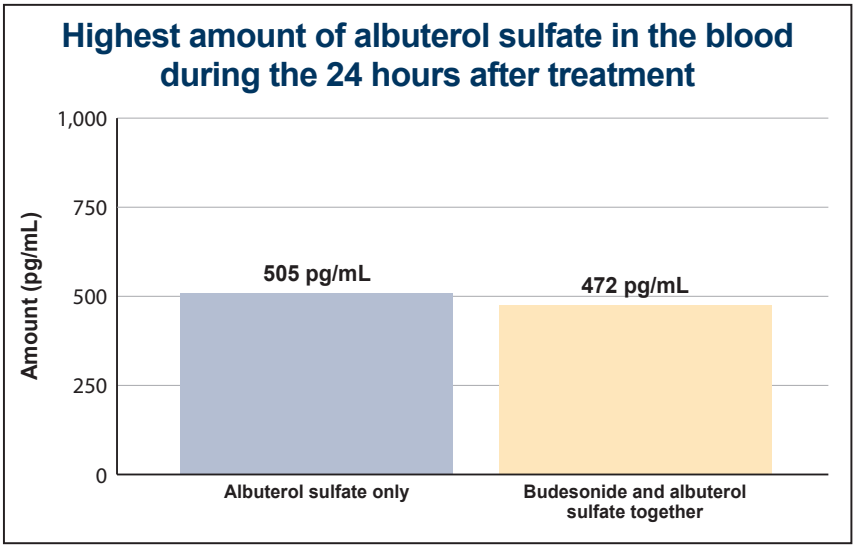
The figure below shows these results.



Albuterol sulfate:

- The highest amount of albuterol sulfate in the blood when the participants took albuterol sulfate only was 505 pg/mL. These results include 90 of the 91 participants.
- The highest amount of albuterol sulfate in the blood when the participants took budesonide and albuterol sulfate together was 472 pg/mL. These results include 89 of the 91 participants.

The figure below shows these results.



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 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.

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.

One of the participants left the study before the researchers could study his or her medical problems. So, the below results are for only 90 of the 91 participants.

How many participants had serious adverse reactions?

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

None of the participants died during the study.

How many participants had adverse reactions?

There were 16.7% of participants who had adverse reactions during the study. This was 15 out of 90 participants.

The table below shows how many participants had adverse reactions during the study.

Most common adverse reactions during the study

	Budesonide only (out of 90 participants)	Albuterol sulfate only (out of 90 participants)	Budesonide and albuterol sulfate together (out of 90 participants)
How many participants had adverse reactions during the study?	5.6% (5)	5.6% (5)	10.0% (9)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)	0.0% (0)
How many participants stopped treatment due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions did the participants have?

The most common adverse reaction during the study was headache.

The table below shows the adverse reactions that happened during the study.

Adverse reactions during the study

	Budesonide only (out of 90 participants)	Albuterol sulfate only (out of 90 participants)	Budesonide and albuterol sulfate together (out of 90 participants)
Headache	2.2% (2)	3.3% (3)	6.7% (6)
Dizziness	0.0% (0)	1.1% (1)	3.3% (3)
Feeling sleepy or sleeping for long periods of time	0.0% (0)	0.0% (0)	1.1% (1)
Feeling tired	0.0% (0)	0.0% (0)	1.1% (1)
Having low energy	0.0% (0)	0.0% (0)	1.1% (1)
Nausea	0.0% (0)	0.0% (0)	1.1% (1)
Cough	1.1% (1)	0.0% (0)	0.0% (0)
Ear pain	1.1% (1)	0.0% (0)	0.0% (0)
Irregular heartbeat	1.1% (1)	0.0% (0)	0.0% (0)
Throat pain	1.1% (1)	0.0% (0)	0.0% (0)
Feeling hot	0.0% (0)	1.1% (1)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn how budesonide and albuterol sulfate act in the body when taken together.

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 combined treatments of budesonide and albuterol sulfate are ongoing.

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 **"NCT03772223"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6930C00003"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase 1, Randomized, Open-label, Single-dose, 3-way Cross-over Study to Compare the Pharmacokinetics of Budesonide and Albuterol Delivered by PT027 Compared with PT007 and PT008 Administered Separately (LOGAN)

AstraZeneca Protocol Number: D6930C00003

AstraZeneca AB sponsored this study and has its headquarters at 151 85 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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