Clinical Study Results

Research Sponsor: AstraZeneca AB

Drugs Studied: Budesonide and albuterol sulfate

Study Title: A study to learn how budesonide combined with albuterol sulfate acts in the body of healthy participants

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 May 2019 and ended in September 2019. It included 67 participants in the United States.

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 asthma. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

Asthma is a condition that causes the airways to narrow, swell, and create extra mucus. This can cause symptoms such as wheezing, coughing, and difficulty breathing.

The study drugs, budesonide and albuterol sulfate, are inhaled treatments that doctors currently use to help people manage their asthma 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 together may help people who have asthma better manage their asthma symptoms.

To learn more about these drugs, the researchers gave the participants 2 inhaled treatments. One of these treatments was an inhaled drug called Pulmicort, which contained only budesonide. The other treatment was an inhaled combination treatment that contained both budesonide and albuterol sulfate.

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

- How did the study treatments act in the body?
- 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 combined with albuterol sulfate improves the health of people who have asthma.

The researchers asked for the help of healthy men and women. The participants in this study were 18 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 what the participant was taking.

In this study, the participants got 2 inhaled treatments:

- Pulmicort, which contained only budesonide
- Budesonide combined with albuterol sulfate

The study 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. 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.

What happened during the study?

Before the participants took treatment, they visited their study site 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 and checked the participants' vital signs
- took blood and 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

During the study, the participants visited their study site 2 times. Each visit lasted about 24 hours.

At the first visit, the participants took 1 of the below inhaled treatments:

- 80 µg of budesonide combined with 90 µg of albuterol sulfate
- 90 µg of Pulmicort, which contained only budesonide

After the first visit, there was a "washout period" of at least 3 days before the next visit. During this time, the participants did not take any study treatment. This was done so that the study treatment could be "washed out" of their bodies before they took the next treatment.

After the washout period, the participants visited their study site again. At this visit, they took the study treatment that they did not take during the first visit.

Throughout the study, the researchers continued checking the participants' health and asking them how they were feeling.

About 1 week after the participants took their second treatment, they visited their study site 1 final time. 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.

There was 1 participant who left the study before the researchers could measure and compare the study results. This participant left because they did not follow the study guidelines. So, the below results are for only 66 of the 67 participants.

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

How did the study treatments act in the body?

To answer this question, the researchers measured and compared the amount of budesonide in the blood after treatment.

The researchers measured:

- The amount of budesonide in the blood during treatment. This was measured in picogram hours per milliliter, also called pg*h/mL.
- The amount of budesonide in the blood during the 24 hours after treatment. This was measured in pg*h/mL.
- The highest amount of budesonide in the blood during the 24 hours after treatment. This was measured in picograms per milliliter, also called pg/mL.
- How long it took for budesonide to reach its highest amount in the blood. This was measured in hours.

Overall, the researchers found that the amounts of budesonide in the blood were lower when the participants took budesonide combined with albuterol sulfate compared to when they took Pulmicort, which contained only budesonide. They also found that it took a similar amount of time for budesonide to reach its highest amount in the blood when the participants took budesonide combined with albuterol sulfate compared to when they took Pulmicort, which contained only budesonide.

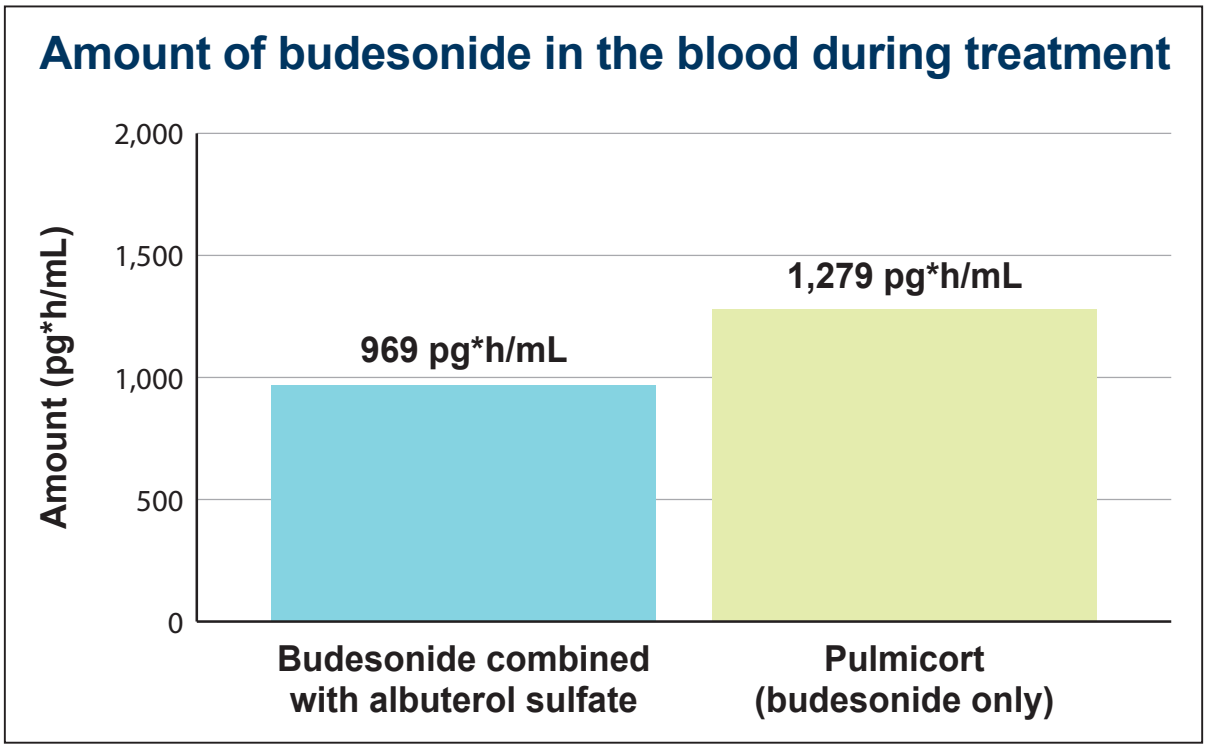
The results of these measurements are listed below.

Amount of budesonide in the blood during treatment

Overall, the researchers found that:

- The amount of budesonide in the blood when the participants took budesonide combined with albuterol sulfate was 969 pg*h/mL.
- The amount of budesonide in the blood when the participants took Pulmicort, which contained only budesonide, was 1,279 pg*h/mL.

The figure below shows these results.

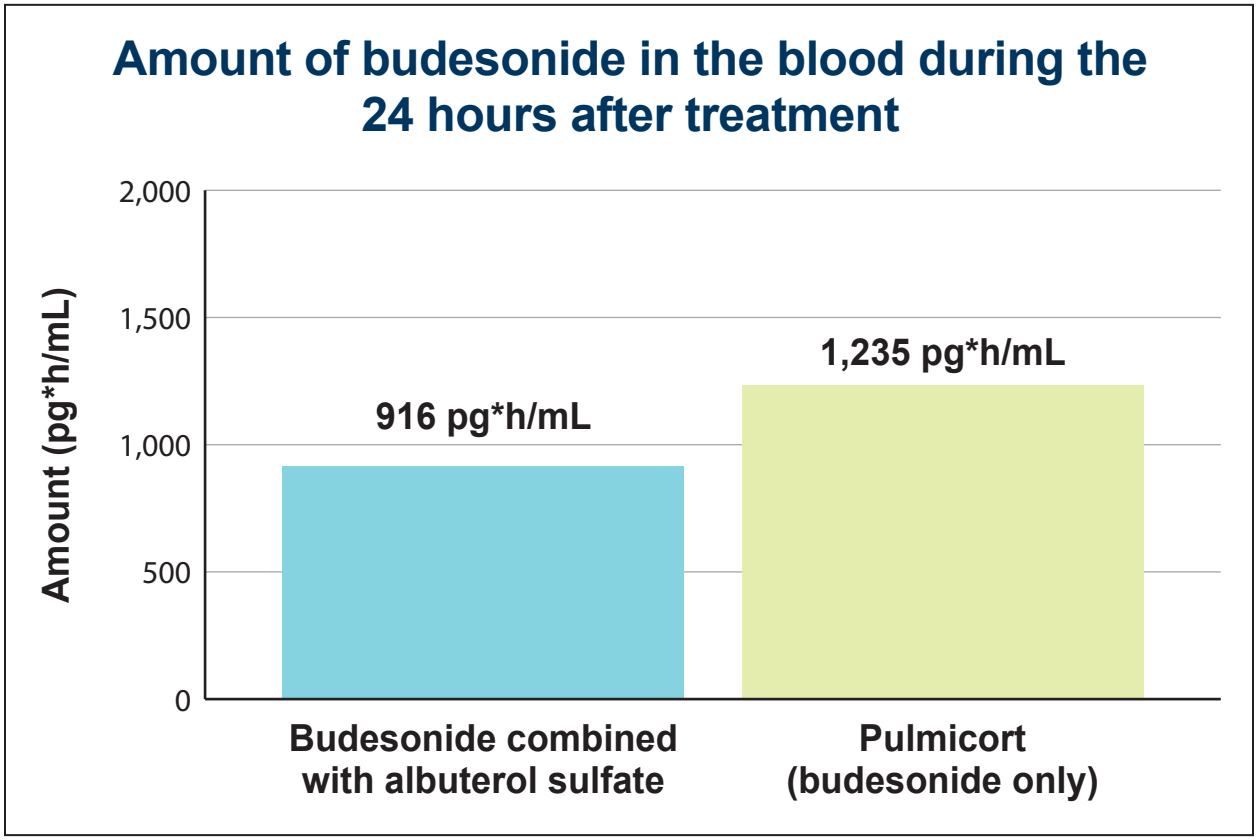


Amount of budesonide in the blood during the 24 hours after treatment

Overall, the researchers found that:

- The amount of budesonide in the blood when the participants took budesonide combined with albuterol sulfate was 916 pg*h/mL.
- The amount of budesonide in the blood when the participants took Pulmicort, which contained only budesonide, was 1,235 pg*h/mL.

The figure below shows these results.

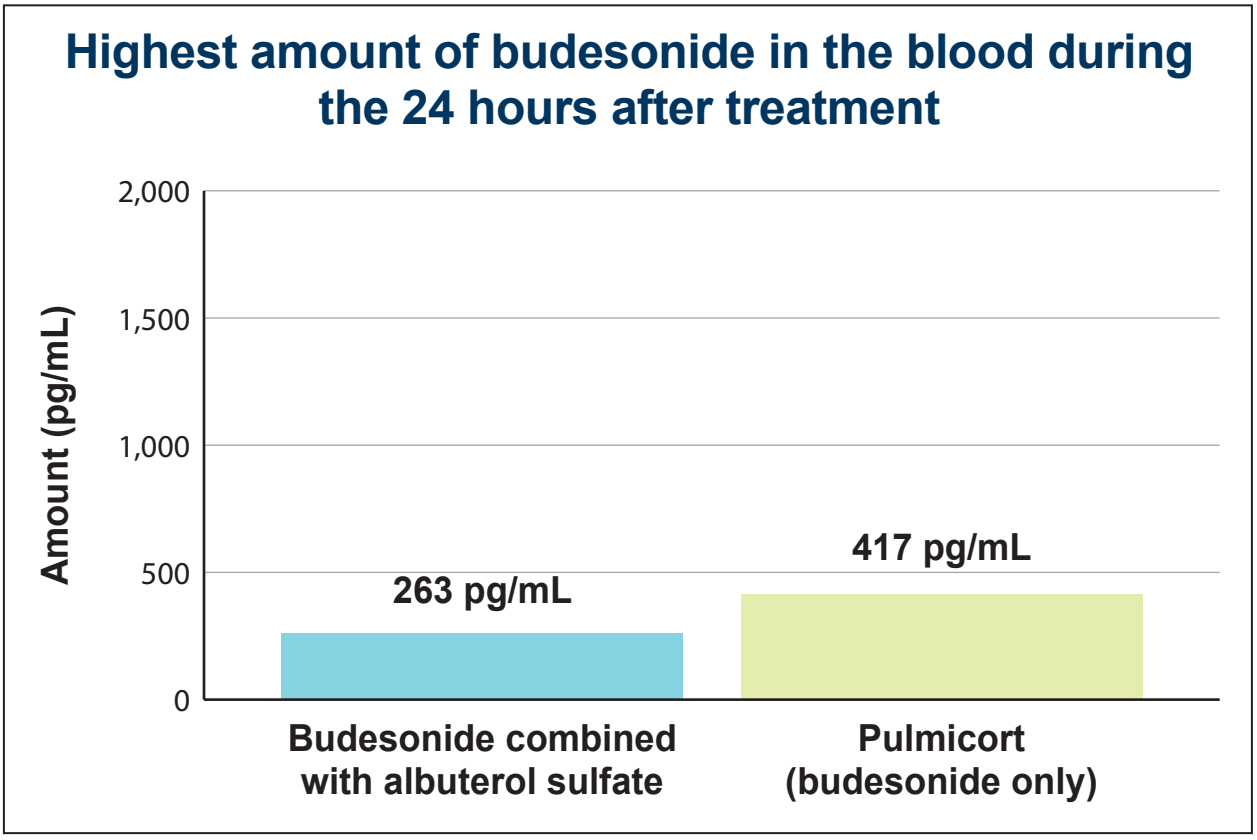


Highest amount of budesonide in the blood during the 24 hours after treatment

Overall, the researchers found that:

- The highest amount of budesonide in the blood when the participants took budesonide combined with albuterol sulfate was 263 pg/mL.
- The highest amount of budesonide in the blood when the participants took Pulmicort, which contained only budesonide, was 417 pg/mL.

The figure below shows these results.

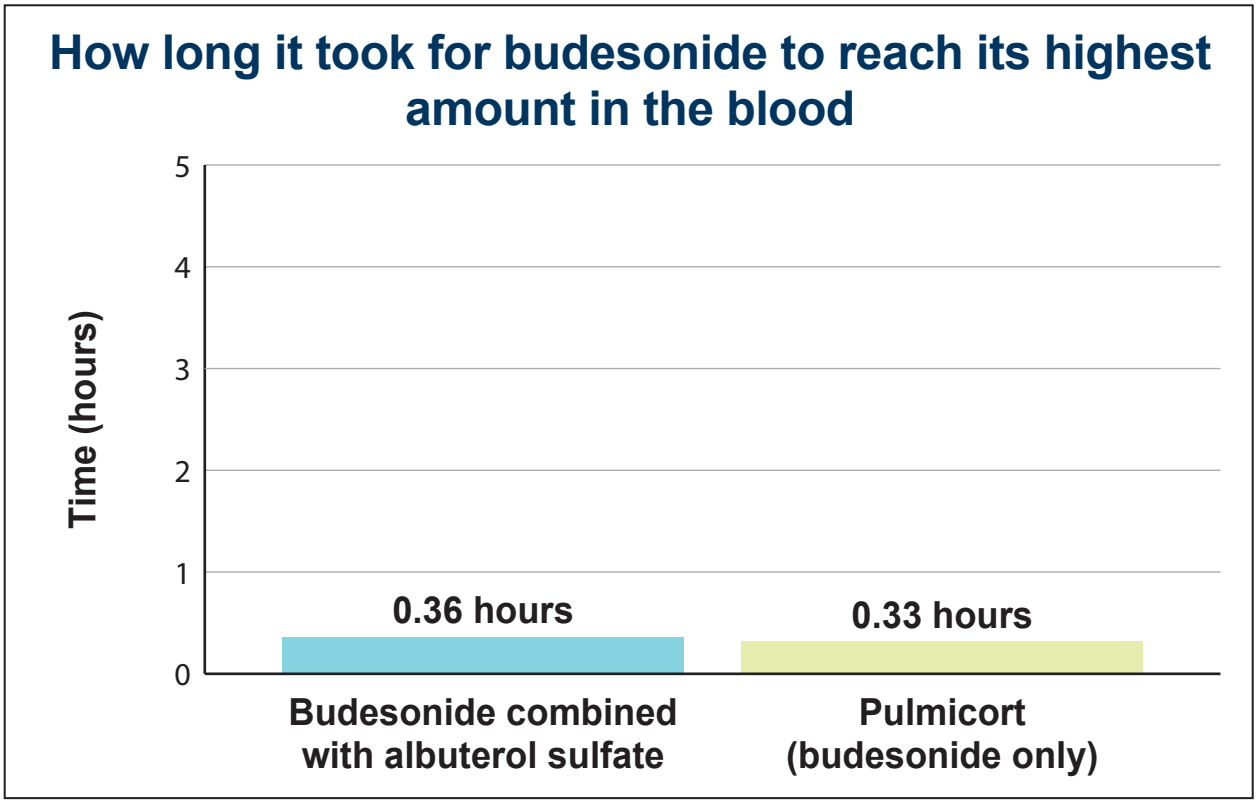


How long it took for budesonide to reach its highest amount in the blood

Overall, the researchers found that:

- It took 0.36 hours for budesonide to reach its highest amount in the blood when the participants took budesonide combined with albuterol sulfate.
- It took 0.33 hours for budesonide to reach its highest amount in the blood when the participants took Pulmicort, which contained only budesonide.

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.

There was 1 participant who left the study before the researchers finished recording the medical problems that happened during the study. This participant left because they did not follow the study guidelines. So, some of the below results are for only 66 of the 67 participants.

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 during the study.

How many participants had adverse reactions?

There were 4.5% of participants who had an adverse reaction during the study. This was 3 out of 67 participants.

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

Adverse reactions during the study

	80 µg of budesonide and 90 µg of albuterol sulfate (out of 67 participants)	90 µg of Pulmicort (budesonide only) (out of 66 participants)
How many participants had adverse reactions during the study?	3.0% (2)	3.0% (2)
How many participants had serious adverse reactions during the study?	0.0% (0)	0.0% (0)
How many participants stopped treatment due to adverse reactions?	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

Adverse reaction	80 µg of budesonide and 90 µg of albuterol sulfate (out of 67 participants)	90 µg of Pulmicort (budesonide only) (out of 66 participants)
Headache	3.0% (2)	1.5% (1)
Feeling tired or sleepy	1.5% (1)	1.5% (1)
Lack of energy	1.5% (1)	0.0% (0)
Chest pain	0.0% (0)	1.5% (1)
Difficulty breathing	0.0% (0)	1.5% (1)

How has this study helped patients and researchers?

This study helped researchers learn how budesonide combined with albuterol sulfate acts in the body, and if this combined treatment is safe to take.

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 of budesonide combined with albuterol sulfate 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 **"NCT03934333"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6930C00011"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase 1, Randomized, Open-label, Single-dose, 2-way Cross-over Study to Compare the Pharmacokinetics of Budesonide Delivered by PT027 Compared with Pulmicort Flexhaler (ELBRUS)

AstraZeneca Protocol Number: D6930C00011

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.