Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Benralizumab

Study Title: A study to learn more about how benralizumab affects breathing in people with severe asthma that was not well controlled by previous treatment

Thank you!

Thank you to the participants who took part in the clinical study for the study drug benralizumab. You and all the participants helped researchers learn more about if benralizumab can help people with severe asthma that is not well controlled by previous treatment.

AstraZeneca AB 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 the participants understand and feel proud of their 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 6 months. But, the entire study took about 1 year and 9 months to finish.

The study started in November 2016 and ended in August 2018. The study included 233 participants in 6 countries, including Chile, Germany, Hungary, the Philippines, South Korea, and 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?

In this study, the researchers wanted to learn more about how benralizumab affects breathing in a large number of participants with severe asthma that was not well controlled by previous treatment. They also wanted to find out if the participants had any medical problems during the study.

Asthma is a disease that can cause swelling in the lungs, which can make it difficult to breathe. Benralizumab is used to treat asthma by reducing this swelling.

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

- How did benralizumab affect the participants' breathing?
- What medical problems did the participants have during the study?

To answer the questions in this study, researchers asked for the help of men and women with severe asthma that was not well controlled by their previous treatment. The participants in this study were 19 to 75 years old.

What kind of study was this?

This was a "double-blind" study. This means none of the participants, doctors, or other study staff knew what treatment each participant got. Some studies are done this way because knowing what treatment the participants are getting can affect the results of the study. When the study ended, the research sponsor found out which treatment participants got so they could create a report of the study results.

In this study, the participants got either benralizumab or a placebo. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who take the drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant got. 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 treatment, the participants visited their study site 4 times. At these visits, the doctors checked to make sure the participants could join the study. The doctors:

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

During treatment, the participants got either benralizumab or a placebo as an injection under the skin. The benralizumab dose was 30 milligrams, also called mg.

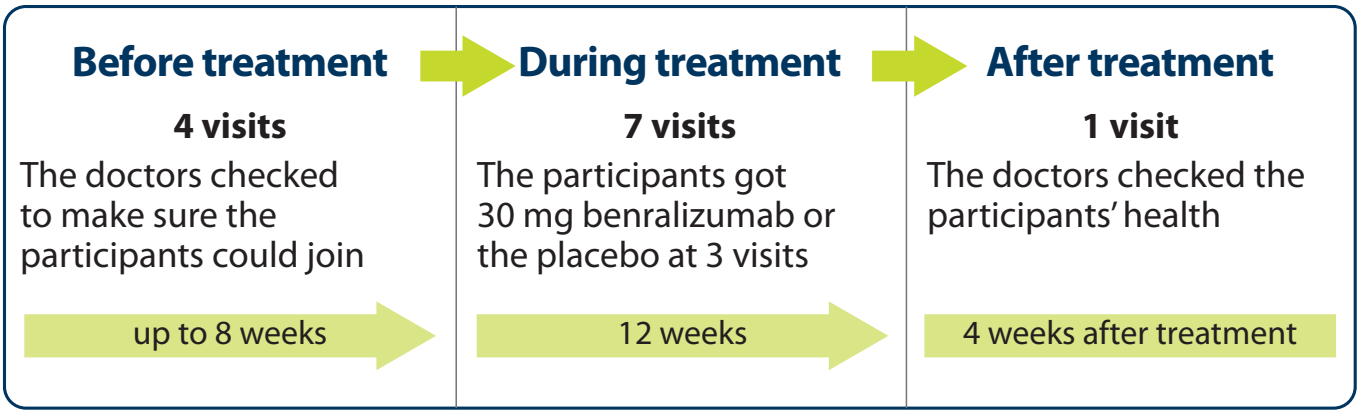
There were 118 participants who got benralizumab and 115 participants who got the placebo.

The participants visited their study site 7 times during the treatment period, but they got benralizumab or the placebo at only 3 visits.

During all of the visits, the doctors checked the lung health of the participants.

After treatment, the participants visited their study site 1 time. This was 4 weeks after their last treatment visit. At this visit, the doctors checked the participants' lung health, overall health, and asked them how they were feeling.

The figure 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 did benralizumab affect the participants' breathing?

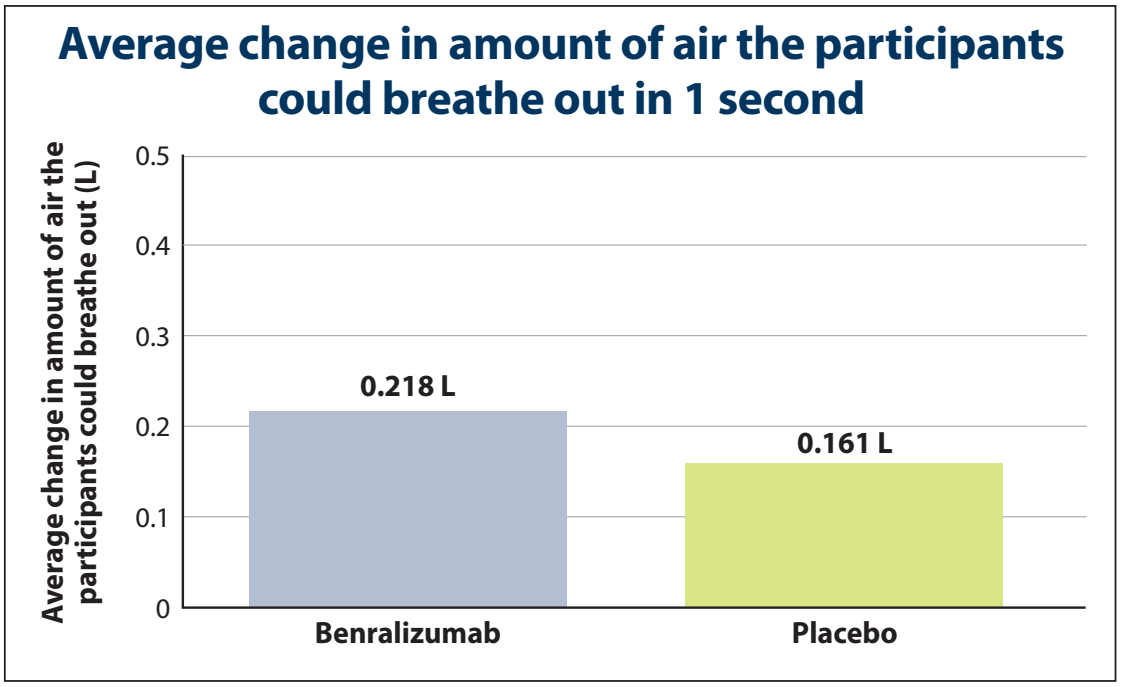
Both the participants who got benralizumab and the participants who got the placebo had their breathing improve. The participants who got benralizumab had greater improvement in their breathing, but the difference between the treatments was too small for the researchers to know if benralizumab improved breathing more than the placebo.

To answer this question, the researchers measured how much air the participants could breathe out in 1 second. They measured the amount of air in liters, also called L. The researchers compared the amount of air the participants could breathe out when they joined the study to the amount of air they could breathe out after they got benralizumab or the placebo.

At the end of the study, the researchers found that the average change in the amount of air the participants could breathe out was:

- 0.218 L more for participants who got benralizumab
- 0.161 L more for participants who got the placebo

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 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.

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 during the study.

How many participants had adverse reactions?

There were 4.3% of participants who had adverse reactions during the study. This was 10 out of 233 participants.

There were 0.4% of participants who stopped treatment because of adverse reactions they had during the study. This was 1 out of 233 participants. This participant was in the benralizumab treatment group and stopped treatment because of the adverse reaction of allergic reaction.

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

Adverse reactions during the study

	30 mg Benralizumab (out of 118 participants)	Placebo (out of 115 participants)	Total (out of 233 participants)
How many participants had adverse reactions during the study?	5.9% (7)	2.6% (3)	4.3% (10)
How many participants stopped treatment because of adverse reactions?	0.8% (1)	0.0% (0)	0.4% (1)

What adverse reactions did the participants have?

The most common adverse reactions were fever, headache, and rash at injection site.

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

Adverse reactions

	30 mg Benralizumab (out of 118 participants)	Placebo (out of 115 participants)
Fever	1.7% (2)	0.0% (0)
Headache	1.7% (2)	0.0% (0)
Rash at injection site	0.8% (1)	0.9% (1)
Allergic reaction	0.8% (1)	0.0% (0)
Dizziness	0.8% (1)	0.0% (0)
Herpes of the mouth	0.8% (1)	0.0% (0)
Itchy skin	0.8% (1)	0.0% (0)
Bleeding outside of the blood vessels	0.0% (0)	0.9% (1)
Redness at injection site	0.0% (0)	0.9% (1)

How has this study helped patients and researchers?

These results helped researchers learn more about how benralizumab works in people with severe asthma that was not well controlled by previous treatment.

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 benralizumab 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 also can be found here.

- www.clinicaltrials.gov. Once you are on the website, type "**NCT02869438**" into the search box and click "**Search**".
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home and Search"**, then type **"2016-002094-36"** in the search box and click **"Search"**.

Full Trial Title: A Multicentre, Randomised, Double-blind, Parallel Group, Placebo-controlled, Phase 3b Study to Evaluate the Onset of Effect and Time Course of Change in Lung Function with Benralizumab in Severe, Uncontrolled Asthma Patients with Eosinophilic Inflammation

AstraZeneca Protocol Number: D3250C00038

AstraZeneca AB, a member of the AstraZeneca Group, 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

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.

CISCRP
One Liberty Square, Suite 1100 • Boston, MA 02109
1-877-MED-HERO • www.ciscrp.org