Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca

Drug Studied: Benralizumab

Study Title: A study to learn more about how an auto-injection device containing benralizumab works for patients with asthma

Thank you!

Thank you to the participants who took part in the clinical study for the auto-injection device containing benralizumab. You and all of the participants helped researchers learn more about using benralizumab in an auto-injection device to help people with asthma.

AstraZeneca 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 for you.

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 8 months. But, the entire study took about 10 months to finish.

The study started in November 2016 and ended in August 2017. The study included 121 participants in Canada 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?

Researchers are looking for a better way to treat asthma. Before a treatment can be approved for patients 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 more about how an auto-injection device containing benralizumab works in a large number of participants with asthma. 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 a drug that is already approved to treat asthma and can help reduce this swelling. The drug is given through a needle under the skin, also known as an injection.

The drug injection device in this study has not yet been approved for patients to use at the doctor's office or to take at home.

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

- How did the auto-injection device work?
- 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 asthma. The participants in this study were 18 to 75 years old when they joined.

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 in the study took benralizumab through the auto-injection device.

What happened during the study?

Before the study started, the doctors:

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

During the study, the participants took 5 benralizumab treatments through the auto-injection device. All 5 treatments contained 30 milligrams, also known as mg, of benralizumab.

The participants took benralizumab once every 4 weeks for 16 weeks. The first 3 treatments were taken at the study site, and the last 2 treatments were taken at home.

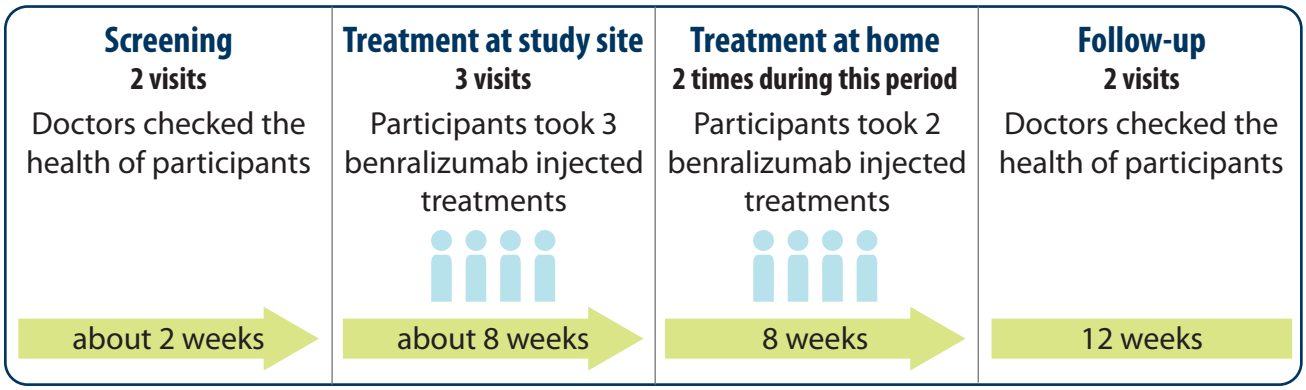
For the first treatment, the doctors gave the participants the benralizumab injection at their study site. The doctors did this so that the participants could ask any questions before they or their caregivers gave an injection.

For the last 4 treatments, either the participants or their caregivers could give the participants the benralizumab injections. Two of these last 4 treatments were taken at home.

At the end of the study, the participants visited their study site twice for follow-up visits over the course of 12 weeks. At those visits, the doctors checked their overall health and asked how they were feeling.

The figure below shows how the study was done.

Open-label study: 121 participants



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.

Some of the participants left this study before it ended. So, the researchers could only study the results for some of the 121 participants. Participants took multiple injections during the study, so there were more auto-injection devices used than there were participants.

How did the auto-injection device work?

To answer this question, the researchers:

- asked the participants and their caregivers if they were able to use the auto-injection devices for the last 2 treatments at home
- analyzed the auto-injection devices after the last treatment to make sure they still worked correctly
- analyzed the auto-injection devices throughout the study that had been reported as not working correctly

At the end of the study, the researchers found that:

- 93.1% of the participants and their caregivers reported that they had been able to use the auto-injection devices for the 2 treatments at home.
- 96.6% of the auto-injection devices worked correctly at week 16, which was the final treatment at home.
- 1.5% of the auto-injection devices were reported as not working correctly. Researchers thought 7 of these were caused by a mistake made by the user, 1 was a manufacturer defect, and 1 did not work correctly due to other reasons.

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 treatment. 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.

How many participants had serious adverse reactions that doctors thought were related to study treatment?

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 that doctors thought were related to study treatment?

There were 10.7% of participants who had adverse reactions during the study. This was 13 of 121 participants.

There were 0.8% of the participants who stopped treatment because of adverse reactions they had during the study. This was 1 of 121 participants.

What adverse reactions did the participants have that study doctors thought were related to study treatment?

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

Adverse reactions	
	Total (out of 121 participants)
Administration site pruritus	1.7% (2)
Injection site pruritus	1.7% (2)
Pain at injection site	1.7% (2)
Swelling at injection site	1.7% (2)
Tiredness	1.7% (2)
Administration-related reaction	0.8% (1)
Headache	0.8% (1)
Rash with blisters	0.8% (1)
Redding of skin at injection site	0.8% (1)
Swelling in the body	0.8% (1)

Administration site pruritus, injection site pruritus, pain at injection site, swelling at injection site, administration-related reaction, and reddening of skin at injection site are similar medical problems. They can include itching, pain, redness, or swelling where the injection was given.

How has this study helped patients and researchers?

These results helped the researchers learn more about using benralizumab in an auto-injection device to help people with asthma.

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 the auto-injection device are not planned at the time 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 **"NCT02918071"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D3250C00031"** into the search box, and click **"Find a Study"**.

Full study title: A Multicenter, Open-label, Functionality, Reliability and Performance Study of a Single-use Auto-Injector with Home-administered Subcutaneous Benralizumab in Adult Patients with Severe Asthma (GRECO)

AstraZeneca protocol number: D3250C00031

AstraZeneca 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 participants.

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 patients for clinical studies, nor is it involved in conducting clinical studies.

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