

**Research sponsor:** AstraZeneca AB

**Drug studied:** Benralizumab

**Short study title:** A study to compare how 2 different injection devices affect the amount of benralizumab in the body

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## ***Thank you!***

Thank you to the participants who took part in this clinical trial for the study drug benralizumab. This study started in January 2017 and ended in July 2017.

AstraZeneca AB sponsored this study and thinks it is important to share the results of this study with you and the public. An independent, nonprofit 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 this study and have questions about the results, please speak with the doctor or staff at your study site.

## **Why was the research needed?**

In this study, the researchers wanted to compare how benralizumab acts in the body when it is taken in 2 different injection devices. They also wanted to find out if the participants had any medical problems during this study.

Benralizumab is an approved drug that is used to treat asthma. Asthma is a disease that can cause swelling in the lungs, which can make it difficult to breathe.

The main question the researchers wanted to answer in this study was:

- How did benralizumab act in the body when taken in 2 different injection devices?

## 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.

A computer program was used to randomly choose the injection device treatment each participant took. Researchers do this so that comparing the results of each treatment is as accurate as possible.

## What happened during this study?

Before this study started, the doctors did a physical examination to make sure the participants could join this study. They also took blood and urine samples and checked the heart health of participants using an electrocardiogram, also known as an ECG. The doctors also asked about the medical history of the participants, how they were feeling, and what medicines they were taking.

The participants were in this study for about 3 months. They visited their study site 11 times.

There were 2 treatments in this study. Both treatments had the same dose of benralizumab. But, the treatments were taken in different injection devices. The participants took 1 of these 2 treatments once during this study.

The participants had a follow-up visit at the end of this study. During this visit, the doctors checked the health of the participants again.

## What were the study results?

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.

## **How did benralizumab act in the body when taken in 2 different injection devices?**

The researchers wanted to learn how benralizumab acts in the body when taken in 2 different injection devices. So, for both treatments, they measured:

- the average amount of benralizumab in the blood
- the highest amount of benralizumab in the blood
- how long it took for benralizumab to reach its highest amount in the blood

In general, the researchers found that the 2 different injection device treatments of benralizumab acted similarly in the body.

## **What medical problems did the participants have?**

The medical problems participants have during clinical studies that the doctors think might be related to the study drug are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study 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 adverse reactions that happened in this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. The websites listed at the end of this summary may have other information about medical problems that happened in this study.

## **How has this study helped patients and researchers?**

This study helped researchers learn how benralizumab acts in the body when it is taken in 2 different injection devices.

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.

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 there.

- [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type “**NCT02968914**” into the search box and click “**Search**”.
- [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu) Once you are on the website, click “**Home & Search**”, then type “**2016-002955-52**” in the search box and click “**Search**”.

**The full title of your study is:** A Multicenter, Randomized, Open-Label, Parallel Group Phase 1 Pharmacokinetic Comparability Study of Benralizumab Administered using Accessorized Pre-Filled Syringe (APFS) or Autoinjector (AI) in Healthy Volunteers

**The protocol number of your study is:** D3250C00030

AstraZeneca AB 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 trial 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.



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 510 • Boston, MA 02109  
1-877-MED-HERO • [www.ciscrp.org](http://www.ciscrp.org)