

# Clinical Study Results



**Research Sponsor:** AstraZeneca AB

**Drug Studied:** Benralizumab

**Study Title:** A study to learn about the safety of benralizumab in healthy Chinese participants in China

---

## Thank you!

Thank you to the participants who took part in the clinical study for the study drug benralizumab. 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 April 2019 and ended in August 2019. It included 36 participants in China.

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 diseases of the airways and lungs, such as asthma. Before a drug can be approved in a country for people in that country to take, researchers do clinical studies to find out how safe it is and how it works.

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

The study drug, benralizumab, is a treatment to help people manage their asthma symptoms. At the time of the study, benralizumab was available as an asthma treatment in several countries, but not in China. So, in this study, the researchers wanted to find out about the safety of benralizumab in healthy Chinese participants, and how benralizumab works.

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

- Did the participants' safety results change during the study?
- What medical problems did the participants have during the study?

The answers to the questions in this study and other studies in China are important to know. These answers help researchers in China find out if benralizumab improves the health of people who have asthma and other diseases of the airways and lungs.

The researchers asked healthy Chinese men and women to participate in this study. The participants in this study were 18 to 42 years old when they joined.

## What kind of study was this?

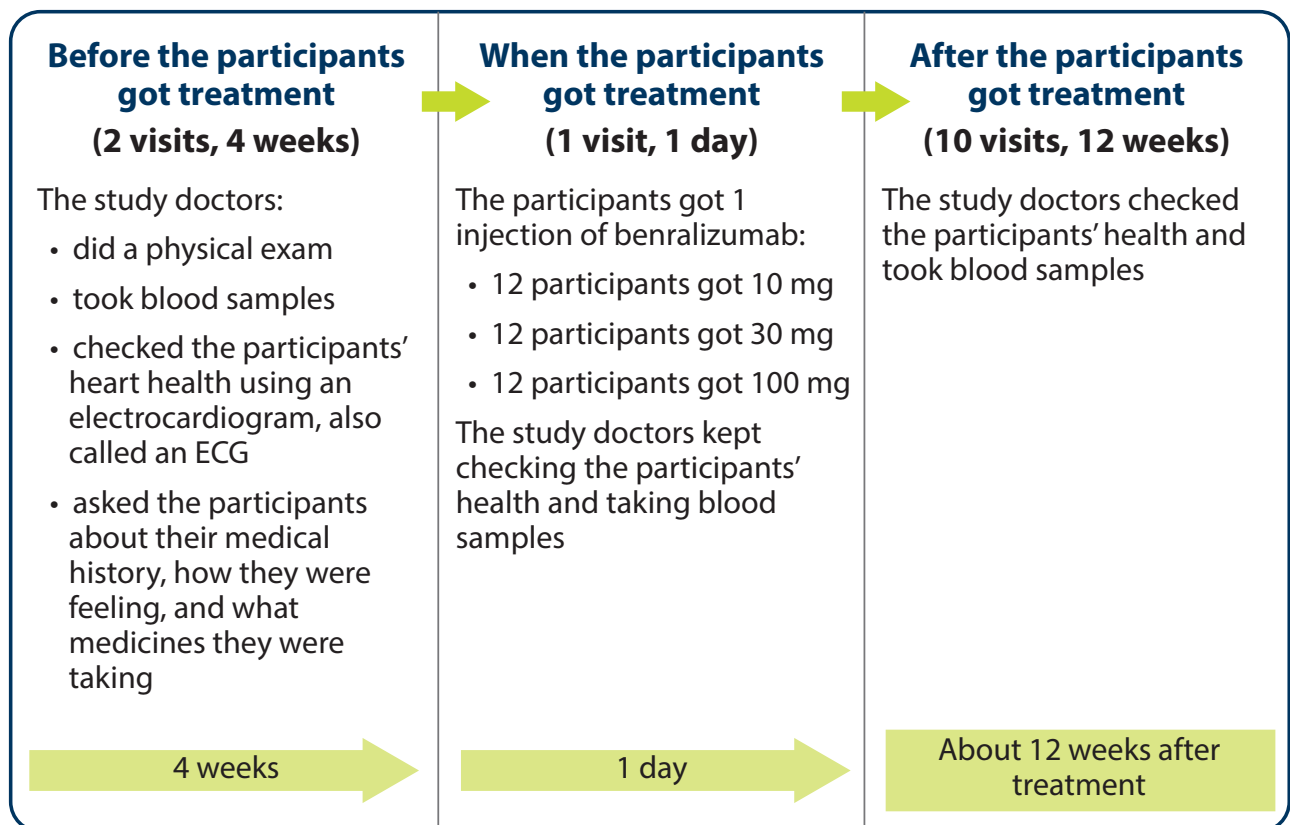
This was a “single-blind” study. This means some of the study staff knew what the participants were getting, but the participants did not.

In this study, the participants got benralizumab through a needle under the skin, also known as an injection. The benralizumab doses were measured in milligrams, also called mg.

A computer program was used to randomly choose the benralizumab dose 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?

The chart 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.

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.

### Did the participants' safety results change during the study?

To answer this question, the researchers compared the results of the tests and measurements that were done before and after the participants got the study drug.

Overall, the researchers found that there were some changes in the participants' results during the study. But, these changes were too small for the researchers to consider them to be meaningful.

The doctors also kept track of the "adverse events" that the participants had during the study. An adverse event is any sign or symptom that participants have during a study.

Doctors keep track of all of the adverse events that happen in studies, even if they do not think the adverse events might be related to the study drug. An adverse event is considered "serious" when it is life threatening, causes lasting problems, or the participant needs hospital care. Adverse events may or may not be caused by the drug in the study.

The websites listed at the end of this summary may have more information about the adverse events that happened during this study.

### Serious adverse events

There were 2.8% of participants who had serious adverse events during the study. This was 1 out of 36 participants. This participant got 100 mg of benralizumab, and had the serious adverse event of a bone fracture in the neck. The researchers did not consider this serious adverse event to be related to the study drug.

None of the participants died during the study.

## Adverse events

There were 27.8% of participants who had adverse events during the study. This was 10 out of 36 participants.

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

**Adverse events during the study**

	<b>10 mg of benralizumab (out of 12 participants)</b>	<b>30 mg of benralizumab (out of 12 participants)</b>	<b>100 mg of benralizumab (out of 12 participants)</b>
How many participants had adverse events?	25.0% (3)	41.7% (5)	16.7% (2)
How many participants had serious adverse events?	0.0% (0)	0.0% (0)	8.3% (1)
How many participants left the study due to adverse events?	0.0% (0)	0.0% (0)	0.0% (0)

The most common adverse event during the study was having a cold. The table below shows each adverse event that happened during the study.

### Adverse events during the study

<b>Adverse event</b>	<b>10 mg of benralizumab (out of 12 participants)</b>	<b>30 mg of benralizumab (out of 12 participants)</b>	<b>100 mg of benralizumab (out of 12 participants)</b>
Having a cold	16.7% (2)	25.0% (3)	8.3% (1)
Bronchitis	8.3% (1)	0.0% (0)	0.0% (0)
Formation of red, itchy patches on the skin	8.3% (1)	0.0% (0)	0.0% (0)
Lip injury	0.0% (0)	8.3% (1)	0.0% (0)
Nausea	0.0% (0)	8.3% (1)	0.0% (0)
Swelling of the skin at the injection site	0.0% (0)	8.3% (1)	0.0% (0)
Bone fracture in the neck	0.0% (0)	0.0% (0)	8.3% (1)
Rash	0.0% (0)	0.0% (0)	8.3% (1)

## What medical problems did the participants have during the study?

This section is a summary of the adverse events the participants had during the study that the study doctors thought might be related to the study drug. These adverse events are called “adverse reactions”. An adverse reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

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 adverse reaction listed in this section is also included in the list of adverse events above.

The websites listed at the end of this summary may have more information about the adverse reaction that happened during this study.

### How many participants had serious adverse reactions?

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

### How many participants had adverse reactions?

There were 2.8% of participants who had adverse reactions during the study. This was 1 out of 36 participants. This participant got 30 mg of benralizumab, and had the adverse reaction of swelling of the skin at the injection site.

## How has this study helped patients and researchers?

This study helped researchers learn about the safety of benralizumab in healthy Chinese participants in China. Overall, during the study, the researchers found that benralizumab acted similarly in the body as it had during previous studies in other countries.

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 can also be found here.

- [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type “**NCT03928262**” into the search box, and click “**Search**”.
- [www.AstraZenecaClinicalTrials.com](http://www.AstraZenecaClinicalTrials.com). Once you are on the website, type “**D3250C00034**” into the search box, and click “**Find a Study**”.

**Full Trial Title:** A Phase 1, Randomized, Single-blind Study to Assess the Safety, Tolerability, and Pharmacokinetics of Benralizumab Administered as Single Subcutaneous Dose in Healthy Chinese Subjects

**AstraZeneca AB Protocol Number:** D3250C00034

**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.



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](http://www.ciscrp.org)