

Study Sponsor: AstraZeneca

Treatment Studied: Benralizumab

Study Purpose: This study was done to learn how 3 new health apps worked for participants with severe asthma taking benralizumab

Protocol Number: D3250R00061

Thank you!

Thank you for taking part in the clinical study for the study drug benralizumab.

AstraZeneca sponsored this study and believes 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 study doctor or staff at your study site.

Overview of this study



Why was the research needed?

Researchers are looking for a better way to detect early changes in the well-being of people with severe asthma after they start getting benralizumab. Before new methods can be approved for people to use, researchers do clinical studies to find out how they work.



What treatments did the participants get?

The participants in this study got benralizumab treatment that had been prescribed by their doctors. They also used 3 new smartphone health apps to measure their well-being and asthma symptoms.



What were the results of this study?

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

> **Did the new apps detect early changes in the participants' well-being after their first dose of benralizumab?**

Only 4 participants completed this study. So, the researchers were not able to conclude whether the new apps could detect early changes in the participants' well-being after they started getting benralizumab.

> **How did the new apps compare with existing methods to measure well-being and asthma symptoms?**

Only 4 participants completed this study. So, the researchers were not able to determine how the new apps compared with existing methods.

> **What medical problems did the participants have during this study?**

The medical problems that the participants had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities.



Where can I learn more about this study?

You can find more information about this study on the websites listed on the last page. When a full report of the study results is available, it also can be found on these websites.



Who took part in this study?

The researchers asked for the help of people with severe asthma. The participants had been prescribed benralizumab by their doctors as part of their health care for their severe asthma. They were about to start their treatment with benralizumab when they joined the study.

The study included 5 participants in the United Kingdom. Of these, 4 participants completed the study.



Why was the research needed?

Researchers are looking for a better way to detect early changes in the well-being of people with severe asthma who start getting benralizumab.

Researchers already did studies that showed benralizumab worked for the people with severe asthma who were in those studies. In this study, the researchers wanted to find out how 3 new smartphone health apps work in detecting these early changes.

Asthma is a long-term lung disease that causes the airways to narrow and causes inflammation in the lungs. This can make it difficult to breathe. People who have asthma may wheeze, cough, and have shortness of breath.

Inflammation in the lungs can lead to high levels of white blood cells called eosinophils. The study drug, benralizumab, can help get rid of the extra eosinophils to help control asthma symptoms.

Currently, people taking benralizumab prescribed by their doctors are invited to fill in questionnaires about their well-being and asthma symptoms. They do this at a visit with their doctors 4 weeks after getting their first dose of benralizumab. Changes in well-being that happen before this visit are called “early” changes. If doctors are able to learn about early changes in well-being, this could improve health care for people with severe asthma.

In this study, the researchers wanted to find out if 3 new smartphone health apps were able to detect early changes in the well-being of participants with severe asthma. All of the participants were starting treatment with benralizumab.

The new health apps in this study were:

- > PROACT, an app that uses videos and messages from the participants to record their emotions
- > uMotif, an app with a questionnaire for participants to record their health data
- > iSpirometry, an app that captures data from a device that the participants use to measure their lung function



What was the purpose of this study?

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

- > Did the new apps detect early changes in the participants' well-being after their first dose of benralizumab?
- > How did the new apps compare with existing methods to measure well-being and asthma symptoms?
- > What medical problems did the participants have during this study?

The answers to these questions are important to evaluate before other studies can be done to find out if the new apps help improve health care for people with severe asthma.



What treatments did the participants get?

In this study, all of the participants got a single dose of benralizumab prescribed by their doctors based on the participants' symptoms. The participants got benralizumab as an injection.

This was an "observational" study. This means the researchers did not change any treatments the participants were already getting or were planned to get as part of their health care.



What happened during this study?

Each participant was in the study for up to 6 weeks. But, the entire study took 5 months to finish. The study started in December 2019 and ended in April 2020.

The researchers ended the study earlier than planned because of the COVID-19 pandemic. As a result, the study did not include as many participants as the researchers had expected.

About 2 weeks before the participants got study treatment, they visited their doctors once. At this visit, the doctors made sure the participants could join the study. The participants:

- > filled in a survey about their asthma symptoms and activities
- > learned how to use the new apps

Throughout the study, the participants:

- > answered a questionnaire about their asthma symptoms once a week
- > used the PROACT and iSpirometry apps every morning
- > used the PROACT and uMotif apps every evening

While the participants were getting study treatment, they visited their doctors once. This part of the study lasted 4 weeks. At this visit, the participants:

- > got 1 injection of benralizumab
- > answered 2 questionnaires about their asthma symptoms

About 4 weeks after the participants got study treatment, they visited their doctors once more. This was their last day taking part in the study. At this visit, the participants:

- > answered final questionnaires about their asthma symptoms
- > filled in a survey about their experience and well-being during the study



What were the results of this 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 researchers wanted to answer can be found on the websites listed at the end of this summary. When a 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.

There was 1 participant who did not complete the study. So, the results below are for 4 out of 5 participants.

Did the new apps detect early changes in the participants' well-being after their first dose of benralizumab?

Only 4 participants completed the study. So, the researchers were not able to conclude whether the new apps could detect early changes in the participants' well-being after they started getting benralizumab.

To answer this question, the researchers calculated scores from the PROACT, uMotif, and iSpirometry apps for each participant, and measured how these scores changed during the study. Then, they counted how many participants had improved scores in all 3 apps in the first 2 weeks after getting benralizumab.

Because the study ended early, the researchers could not draw any conclusions from the results.

How did the new apps compare with existing methods to measure well-being and asthma symptoms?

Only 4 participants completed the study. So, the researchers were not able to determine how the new apps compared with the existing methods.

To answer this question, the researchers compared the participants' scores from the PROACT, uMotif, and iSpirometry apps with their scores from the questionnaires they answered during the study. These were:

- > 6-Item Asthma Control Questionnaire, also called ACQ-6
- > St George's Respiratory Questionnaire, also called SGRQ

If the results were similar, this meant that the new apps helped measure the participants' well-being and asthma symptoms as much as the existing methods did.

Because the study ended early, the researchers could not draw any conclusions from the results.



What medical problems happened during this study?

The medical problems participants have during clinical studies that the study doctors think might be related to the study treatments 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 treatments or devices. A lot of research is needed to know whether a treatment or device causes an adverse reaction.

This study was not designed to collect information on adverse reactions that might be related to benralizumab. It was designed to collect information on adverse reactions that might be related to the use of the new apps. But, these adverse reactions are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities.



How has this study helped patients and researchers?

This study helped researchers learn more about using 3 new smartphone health apps to detect early changes in the well-being of participants with severe asthma who have recently started treatment with benralizumab.

This summary only shows information from this 1 study. Other studies may provide new information.

No further clinical studies with these 3 apps were 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 more information about the study results is available, it can also be found here.

- > www.clinicaltrials.gov Once you are on the website, type **"NCT04200326"** into the search box and click **"Search"**.
- > www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D3250R00061"** into the search box, and click **"Find a Study"**.

Full Study Title: TWINKLE: Real-Life First Dose Effect of Fasenra in Patients With Severe Uncontrolled Asthma

AstraZeneca Protocol Number: D3250R00061

National Clinical Trials number: NCT04200326

AstraZeneca sponsored this study and has its headquarters at Cambridge, UK.

The phone number for the AstraZeneca Information Center is +1-877-240-9479.

Thank you!

Clinical study participants and their families 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