Clinical Study Results

Research sponsor: AstraZeneca

Drug studied: Tralokinumab

Study title: A study to learn if tralokinumab is safe to take for patients with severe, uncontrolled asthma

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug tralokinumab. You and all of the participants helped researchers learn more about tralokinumab to help patients with asthma.

AstraZeneca sponsored this study and thinks it is important to share the results of the study with you and the public. 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 scheduled to be in the study for up to about 1 year. But the study ended early, so most of the participants were not in the study for 1 year. The entire study took a little more than 1 year to finish.

The study started in November 2016 and ended in January 2018. The study included 28 participants in Japan.

The study was ended early. This is because the study drug, tralokinumab, is no longer being developed by AstraZeneca for patients with asthma.

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 drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

Asthma is a lung disease that causes redness, swelling, and narrowing of the airways. This can make it difficult to breathe. Different kinds of medicines can be used to treat these asthma symptoms by decreasing redness and swelling in the airways. Tralokinumab is a drug that was created to possibly help reduce redness and swelling in the airways.

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

- What medical problems did participants have during the study?

The researchers asked for the help of men and women with asthma who had at least 1 asthma attack in the past year that required treatment. The participants were taking at least 1 asthma medication for at least 3 months before joining the study.

The participants in the study were 25 to 72 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 treatment the participants were getting.

All of the participants had severe, uncontrolled asthma, and were taking medication for it.

All of the participants in the study got tralokinumab through an injection under the skin.

What happened during the study?

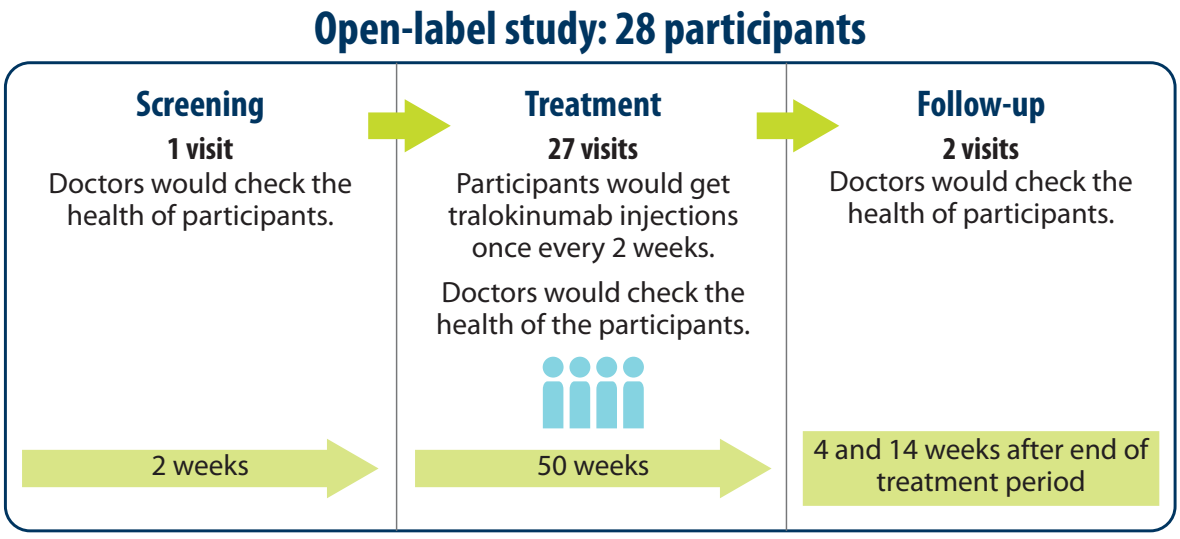
Before the study started, the doctors:

- did a physical examination
- checked the lung health of the participants
- asked the participants about their medical history and asthma symptoms
- asked the participants how they were feeling and what medicines they were taking

During the study, the participants were scheduled to get 2 tralokinumab injections once every 2 weeks for 50 weeks. Each injection had a dose of 150 milligrams, also known as mg, of tralokinumab. All 28 participants got at least 1 dose of the study drug. Two of the 28 participants finished the treatment period, but none of the participants finished the study.

At the end of the study, the participants were scheduled to visit their study site twice for follow-up visits. This was so that the doctors could check the participants' health again and ask about their asthma symptoms.

The figure below shows how the study was scheduled to be 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.

What medical problems did participants have during the study?

This section is a summary of the medical problems the participants had during this study that the study doctors thought might be related to the study drug. 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 more information about the 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.

What adverse reactions did the participants have?

There were 50.0% of participants who had adverse reactions during the study. This was 14 out of 28 participants.

None of the participants stopped taking tralokinumab because of an adverse reaction they had during the study.

The most common adverse reaction was swelling, redness, burning, or itching where the injection was given. This happened in 35.7% of participants. This was 10 out of 28 participants.

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

Adverse reactions that happened during the study

Adverse reaction	Tralokinumab (Out of 28 participants)
Swelling, redness, burning, or itching where the injection was given	35.7% (10)
Pain where the injection was given	3.6% (1)
Fever	3.6% (1)
Joint pain	3.6% (1)
Feeling weak	3.6% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about tralokinumab and if it is safe to take for patients 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 with tralokinumab in people with asthma are not 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. Once you are on the website, type **"NCT02902809"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D2210C00029"** into the search box, and click **"Find a Study"**.

The full title of your study is: A 52-Week, Open-Label, Multicentre Study to Evaluate the Safety of Tralokinumab in Japanese Adults and Adolescents with Asthma Inadequately Controlled on Inhaled Corticosteroid plus Long Acting ß2-Agonist

Protocol number: D2210C00029

AstraZeneca sponsored this study and has its headquarters at
1800 Concord Pike in Wilmington, Delaware.

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.