AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca KK

Drug studied: Tezepelumab

Study Purpose: This study was done to learn about the safety of tezepelumab in Japanese participants with severe asthma

Protocol Number: D5180C00019

Thank you!

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

You and all of the participants helped researchers learn more about tezepelumab to help people with severe asthma.

AstraZeneca KK sponsored this study and believes 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. We hope it helps you understand and feel proud of your important role in medical research.

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 treat severe asthma that is not well controlled. Before a drug can be approved for people to get, researchers do clinical studies to find out how it works and how safe it is.

What treatments did the participants get?

The participants in this study got tezepelumab.

What were the results of this study?

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

- **What signs and symptoms did the participants have during the study?**

  The most common signs and symptoms that the participants had during this study were the common cold and a sore throat.

- **What medical problems happened during the study?**

  There were 3.1% of participants who had medical problems that the study doctors thought might be related to the study drug during the study. This was 2 out of 65 participants. The most common medical problem was redness at the injection site.

More details about the results of this study are included later in this summary.

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 those websites.

Who took part in this study?

The researchers asked for the help of Japanese males and females with severe asthma that was not well controlled. The participants in this study were 15 to 76 years old when they joined. Participants could join the study if they:

- had been using a steroid inhaler for 12 months or more, and at least 1 other treatment to control their asthma for 3 months or more
- had at least 1 severe asthma attack in the last year that caused them to take additional medication or go to the hospital
- had completed a survey that showed that their asthma was not well controlled

The study included 65 participants in Japan.

Why was the research needed?

Researchers are looking for a better way to treat severe asthma that is not well controlled. Before a drug can be approved for people to get, researchers do clinical studies to find out how it works and how safe it is.

Asthma is a disease that causes the airways that carry air in and out of the lungs to become inflamed and narrow. This can make it difficult to breathe. People who have asthma may wheeze, cough, and have shortness of breath.

The study drug, tezepelumab, was designed to help reduce inflammation in the airways in people with asthma. In this study, the researchers wanted to find out if tezepelumab works in Japanese participants with asthma. They also wanted to find out if the participants had any medical problems during the study.

What was the purpose of this study?

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

- What signs and symptoms did the participants have during the study?
- What medical problems did the participants have during the study?

The answers to these questions are important to know before other studies can be done to find out if tezepelumab helps improve the health of Japanese patients with severe asthma that is not well controlled.

What drug did the participants get?

In this study, all of the participants got tezepelumab.

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was getting.

Each participant got tezepelumab through a needle under the skin, also called a subcutaneous injection. They got a total of 13 injections over a period of 1 year.

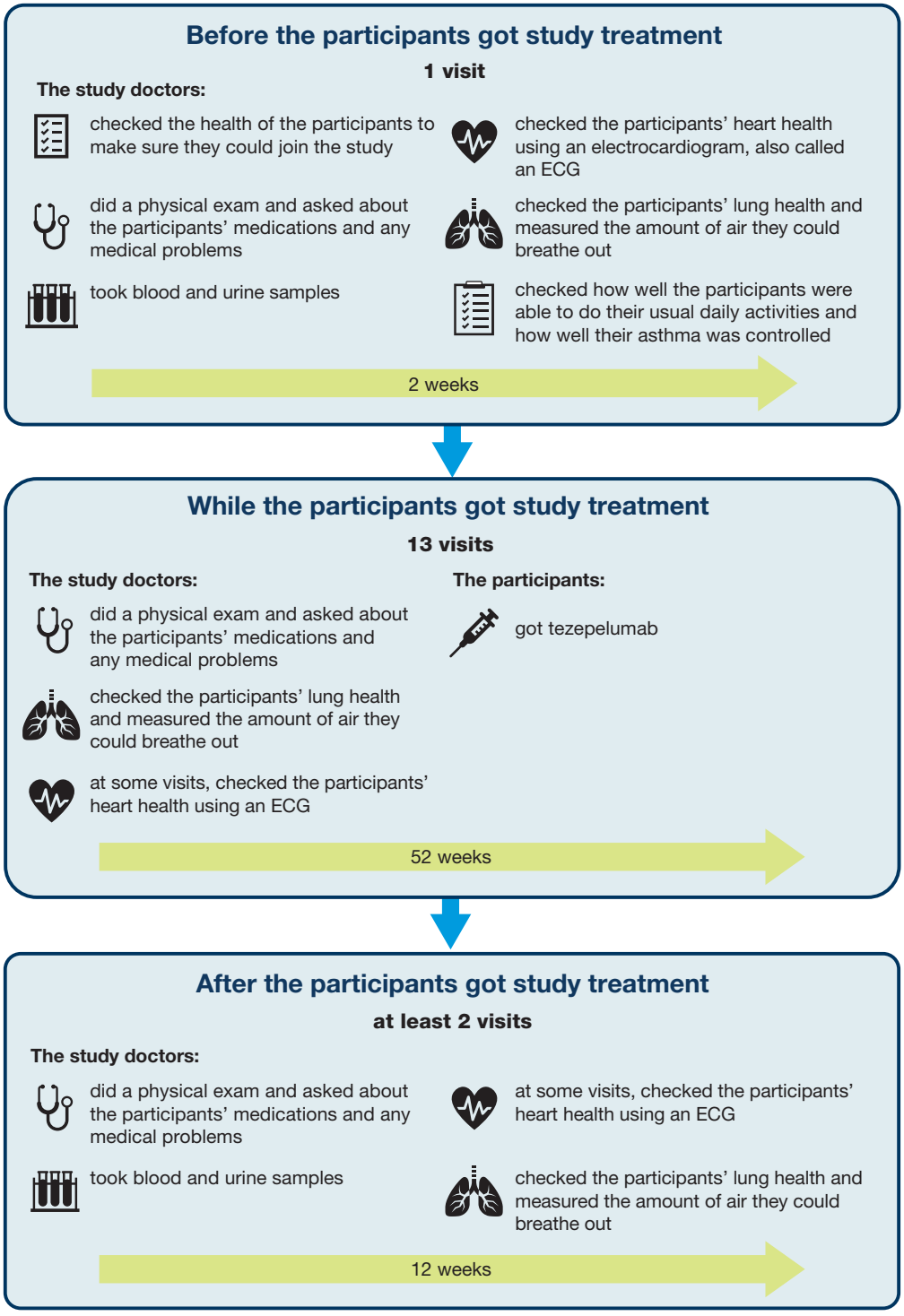
The chart below shows the treatment the participants got.

	Tezepelumab
	65 participants
	Tezepelumab as an injection under the skin
	Once every 4 weeks

What happened during this study?

The participants were in the study for up to 1 year and 3 months. But, the entire study took 22 months to finish. The study started in June 2019 and ended in March 2021.

The chart below shows what happened 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 that researchers wanted to answer can be found on the websites listed at the end of this summary. When 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 signs and symptoms did the participants have during the study?

To answer this question, the study doctors did tests and measurements before and after the participants got tezepelumab. The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also did ECGs to check the participants' heart health. Overall, the study doctors did not think that there were any meaningful changes in the results of these tests and measurements.

The study doctors also kept track of the "adverse events" that the participants had. An adverse event is any sign or symptom that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study drug.

Later in this document, there will be a summary of the adverse events that the study doctors thought might be related to the study drug. This section is a summary of all the adverse events, whether they might be related to the study drug or not. 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. A lot of research is needed to know whether a drug causes an adverse event.

There were 1.5% of participants who stopped getting tezepelumab due to adverse events. This was 1 out of 65 participants.

There were 6.2% of participants who had serious adverse events. This was 4 out of 65 participants.

The serious adverse events were:

- Diarrhea and vomiting caused by a virus
- A swollen area where pus has collected in the lungs
- Infection of the tonsils
- Irregular and uncoordinated contractions of the upper chambers of the heart, which may cause an irregular heartbeat

There were 64.6% of participants who had adverse events. This was 42 out of 65 participants.

The most common adverse events were:

- Common cold
- Sore throat
- Back pain
- Bruising
- A painful, blistering rash in one part of the body
- Inflammation of the nose, throat, and voice box

What medical problems happened during this 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 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for tezepelumab.

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.

Did any adverse reactions happen during this study?

How many participants had adverse reactions?

- There were 3.1% of participants who had adverse reactions. This was 2 out of 65 participants. These 2 participants both had redness at the injection site.

How many participants had serious adverse reactions?

- None of the participants had serious adverse reactions.

How many participants left the study due to adverse reactions?

- None of the participants left the study due to adverse reactions.

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of tezepelumab in Japanese participants with severe asthma that is not well controlled.

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 tezepelumab are planned.

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 **"NCT04048343"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5180C00019"** into the search box, and click **"Find a Study"**.

Full Study Title: Long-term Safety of Tezepelumab in Japanese Subjects With Inadequately Controlled Severe Asthma (NOZOMI)

AstraZeneca Protocol Number: D5180C00019

National Clinical Trials Number: NCT04048343

AstraZeneca KK sponsored this study and has its headquarters in Osaka, Japan.

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.

CISCRP

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.

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Version 1.0 2021_09_17