AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Tezepelumab

Study Purpose: This study was done to learn how different doses of tezepelumab pass through, break down and leave the body of healthy Chinese participants

Protocol Number: D5180C00020

Thank you!

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

AstraZeneca AB 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.

Who took part in this study?

The researchers asked for the help of healthy Chinese men and women. The participants in this study were 18 to 43 years old when they joined.

The study included 48 participants in China.

Why was the research needed?

Researchers are looking for a better way to treat some conditions caused by inflammation. 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.

The study drug, tezepelumab, was designed to help reduce inflammation. Researchers are currently doing studies to find out if tezepelumab helps people with any condition from a group of 5 conditions caused by inflammation, including severe asthma.

Even though there have been several studies of tezepelumab worldwide, there have been no studies specifically looking at how it works in Chinese participants. The purpose of this study was to find out more about how tezepelumab passes through, breaks down and leaves the body in healthy Chinese participants.

What was the purpose of this study?

In this study, the researchers wanted to learn how tezepelumab passes through, breaks down, and leaves the body in healthy Chinese participants when it is given as an injection at 3 different doses.

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

- How did each of the 3 different doses of tezepelumab pass through, break down and leave the participants' bodies
- 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 people who have conditions caused by inflammation.

What treatments did the participants get?

In this study, all of the participants got either tezepelumab or a placebo through a needle under the skin, also called an injection. A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure any of the effects they see in the participants who get the drug are actually caused by the drug.

This was a "double-blind" study. This means none of the participants, researchers, study doctors, or other study staff knew what treatment each participant was getting. Some studies are done this way because knowing what treatment the participants are getting can affect the results of the study. When the study ended, the research sponsor found out which treatment the participants got so they could create a report of the study results.

A computer program was used to randomly choose the treatment 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.

The chart below shows the treatments the researchers planned to study. The doses of tezepelumab were measured in milligrams, also called "mg".

	Group 1	Group 2	Group 3	Placebo
	12 participants	12 participants	12 participants	12 participants
	70 mg of tezepelumab	210 mg of tezepelumab	420 mg of tezepelumab	placebo
	A single injection under the skin			

What happened during this study?

The study started in May 2020 and ended in October 2020.

Before the participants got study treatment, they visited their study site 1 time. This part of the study lasted for up to 4 weeks. At this visit, the study doctors made sure the participants could join the study. They also:

- did physical exams and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG

The study doctors also did these tests and measurements throughout the study.

While the participants got study treatment, they visited their study site 1 time. This part of the study lasted for 3 days. The participants stayed at the study site for 2 nights. They got a single injection of their study treatment on the second day of their stay.

After the participants got study treatment, they visited their study site 12 times. At these visits, the study doctors checked the health of the participants and took blood samples. This part of the study lasted for up to 16 weeks.

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.

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.

The websites listed at the end of this summary may have more information about the study results.

Because the participants who got the placebo did not have any tezepelumab in their blood, their results are not included in this part of the summary.

How did each of the 3 different doses of tezepelumab pass through, break down and leave the participants' bodies?

To answer this question, the study doctors took blood samples from the participants before their injection, and at several times after their injection.

The researchers then measured how the amount of tezepelumab changed in the participants' blood over time. From these results, the researchers calculated:

- the average highest concentration of tezepelumab in the participants' blood
- the average total amount of tezepelumab in the participants' blood
- the average total amount of tezepelumab in the participants' blood between the first and last blood samples taken during the study

The researchers found that these measurements were different between the groups. All of these measurements were lowest in the participants who got the low dose of tezepelumab and highest in the participants who got the high dose of tezepelumab.

The researchers also calculated:

- how long it took to reach the highest concentration of tezepelumab in the participants' blood
- how long it took for the concentration of tezepelumab to reduce by half
- how quickly tezepelumab left the participants' blood
- how far tezepelumab spread out in the participants' bodies

The researchers found that these measurements were similar among all of the groups, even though they got different doses of tezepelumab.

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".

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.

During this study, **none of the participants had an adverse reaction**.

How has this study helped patients and researchers?

This study helped researchers learn more about how tezepelumab passes through, breaks down and leaves the bodies of healthy Chinese participants when it was given as an injection at 3 different doses.

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 **"NCT04362410"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D5180C00020"** into the search box and click **"Find a Study"**.

Full Study Title: A Phase 1, Single Centre, Double-blind, Randomized, Placebo-controlled Parallel-group Study to Evaluate the Pharmacokinetics, Safety, Tolerability and Immunogenicity of Tezepelumab after Single-Dose Subcutaneous Administration in Healthy Chinese Subjects (DIRECTION-CK)

AstraZeneca AB Protocol Number: D5180C00020

National Clinical Trials Number: NCT04362410

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 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_2022_03_16