Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Tezepelumab

Study Title: A study to learn about the levels of tezepelumab in the blood when the drug is injected 1 time by different methods

Thank you!

Thank you to the participants who took part in the clinical study for the study drug tezepelumab. 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 study doctor or staff at your study site.

Who took part in the study?

The researchers asked for the help of healthy men and women. The participants in this study were 19 to 65 years old when they joined.

The study included 315 participants at 1 site in Germany.

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

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

There are treatments that can help people who have asthma manage their symptoms. But, these treatments may not help some people control their symptoms and may cause medical problems.

The study drug, tezepelumab, is being developed as a treatment for asthma. Researchers think that tezepelumab may help people who have asthma to better manage their symptoms.

In this study, the researchers wanted to learn about the levels of tezepelumab in the blood when the drug was injected by 3 different methods.

What was the purpose of this study?

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

- What were the levels of tezepelumab in the blood when the drug was injected by 3 different methods?
- What medical problems happened during the study?

The answers to these questions are important to find out whether the 3 different injection methods of tezepelumab perform in the same way.

What treatments did the participants get?

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

In this study, all of the participants got tezepelumab through a needle under the skin. This is also known as an injection. The participants got the same amount of tezepelumab through 1 of 3 different injections.

The first group of participants got an injection through a vial and syringe filled by the doctors.

The second group of participants got an injection through a pre-filled syringe. This syringe had a plunger at its top and a protective layer around the needle. This type of syringe is known as an accessorized syringe. Doctors use accessorized syringes to increase the safety of a syringe and reduce the chance of injury.

The third group of participants got an injection through a device, called an auto-injector. Auto-injectors are devices that deliver injections by a button push or by pressing the device against the injection site.

All of the injections were given in liquid form. The amount of liquid was measured in milliliters, also called mL. The amount of tezepelumab within the liquid was measured in milligrams, also called mg. All of the participants got the same amount of liquid and the same amount of tezepelumab within the liquid.

The chart below shows the treatments the participants got.

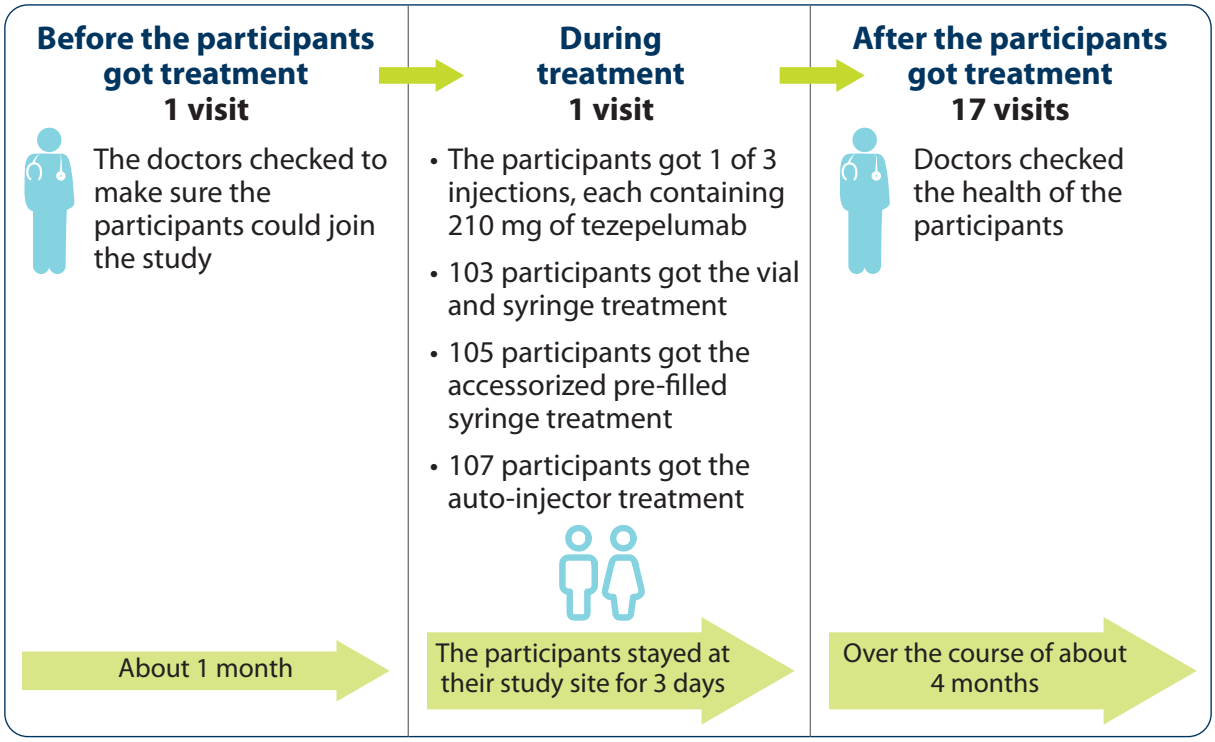
Treatment	Drug amount	Amount of liquid injection
Vial and syringe (103 participants)	210 mg of tezepelumab	1.9 mL of liquid
Accessorized pre-filled syringe (105 participants)	210 mg of tezepelumab	1.9 mL of liquid
Auto-injector (107 participants)	210 mg of tezepelumab	1.9 mL of liquid

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.

What happened during the study?

The study started in June 2019 and ended in December 2019.

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.

Some of the participants either left the study before it ended or did not follow the study guidelines. So, the researchers were not able to collect the below results for all 315 participants.

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

What were the levels of tezepelumab in the blood when the drug was injected by 3 different methods?

To answer this question, the researchers measured the levels of tezepelumab in the blood after the participants got treatment.

The researchers measured:

- The level of tezepelumab in the blood over time. This was measured in microgram days per milliliter, also known as µg•day/mL.
- The highest level of tezepelumab in the blood. This was measured in micrograms per milliliter, also known as µg/mL.

Overall, the researchers found that these levels were similar among the 3 treatments.

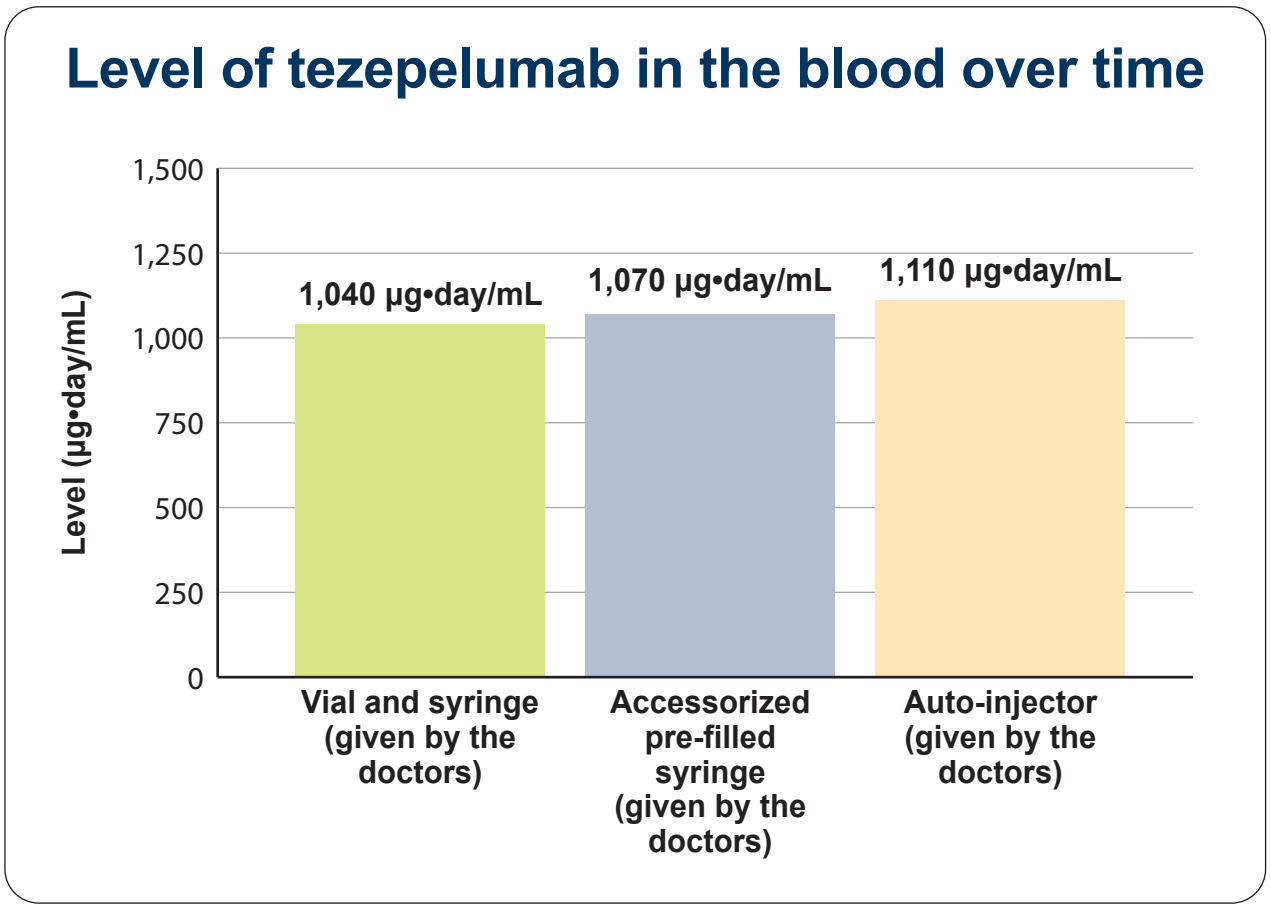
The results of these measurements are listed below.

Level of tezepelumab in the blood over time

Overall, the researchers found that the level of tezepelumab in the blood over time was:

- 1,040 µg•day/mL for the participants who got tezepelumab through the vial and syringe. This was for 103 out of 103 participants.
- 1,070 µg•day/mL for the participants who got tezepelumab through the accessorized pre-filled syringe. This was for 104 out of 105 participants.
- 1,110 µg•day/mL for the participants who got tezepelumab through the auto-injector.

The figure below shows these results.

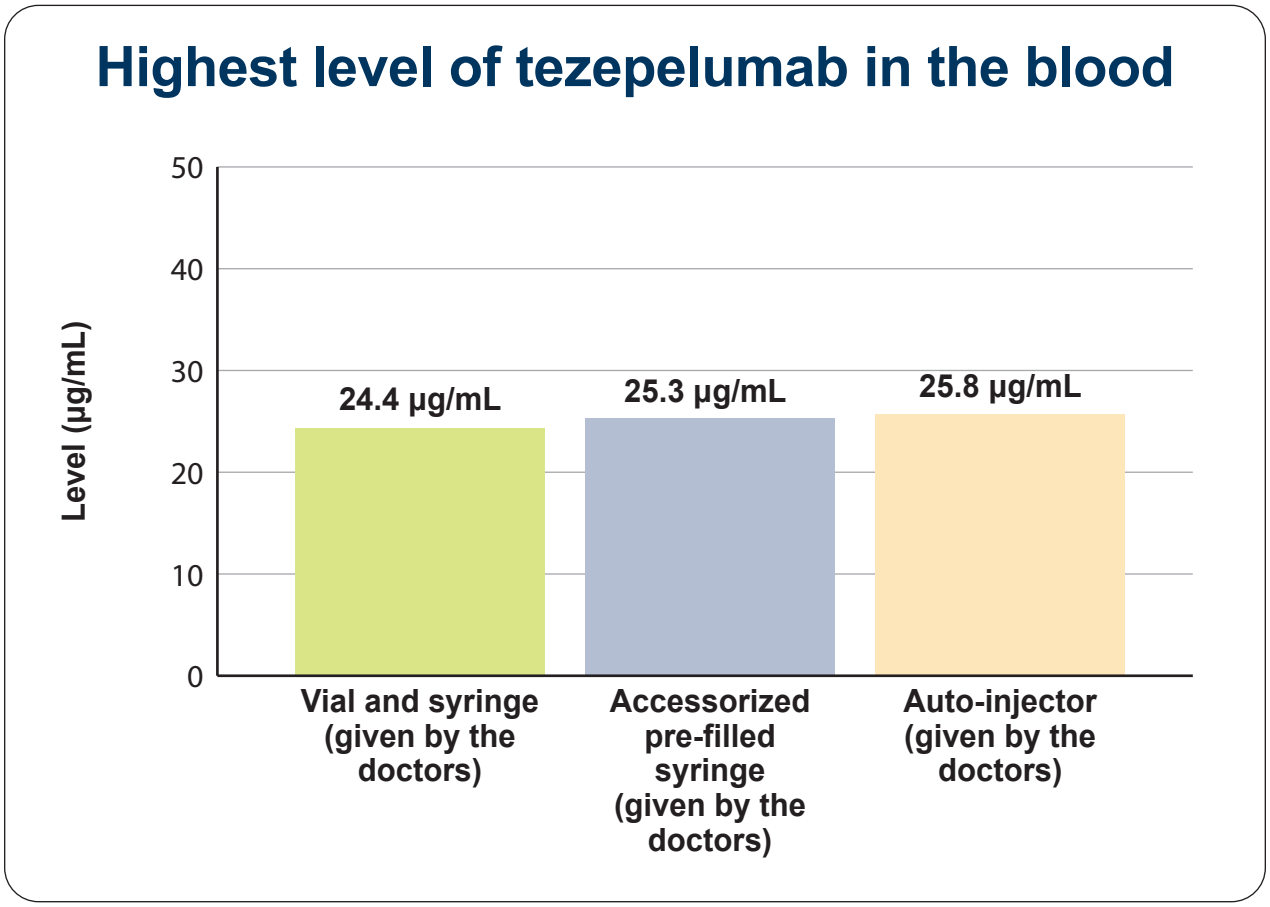


Highest level of tezepelumab in the blood

Overall, the researchers found that the highest level of tezepelumab in the blood was:

- 24.4 µg/mL for the participants who got tezepelumab through the vial and syringe. This was for 103 out of 103 participants.
- 25.3 µg/mL for the participants who got tezepelumab through the accessorized pre-filled syringe. This was for 105 out of 105 participants.
- 25.8 µg/mL for the participants who got tezepelumab through the auto-injector. This was for 105 out of 107 participants.

The figure below shows these results.



What medical problems happened during the 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 treatments. 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 treatments. A lot of research is needed to know whether a treatment causes an adverse reaction. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the treatments.

Some of the participants either left the study before it ended or did not follow the study guidelines. So, the researchers were not able to study the medical problems for all 315 participants.

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?

There were 15.0% of participants who had at least 1 adverse reaction during this study. This was 47 out of 314 participants.

None of the participants had serious adverse reactions related to the study drug during this study.

None of the participants died during this study.

The table below shows how many participants had adverse reactions.

Adverse reactions during the study

	Vial and syringe (out of 103 participants)	Accessorized pre-filled syringe (out of 105 participants)	Auto-injector (out of 106 participants)
How many participants had adverse reactions?	10.7% (11)	18.1% (19)	16.0% (17)
How many participants had serious adverse reactions related to study drug?	0.0% (0)	0.0% (0)	0.0% (0)
How many participants left this study due to adverse reactions?	0.0% (0)	0.0% (0)	0.0% (0)

What adverse reactions happened during this study?

The most common adverse reaction was a common cold.

The table below shows the adverse reactions that happened in at least 2 participants during this study. There were other adverse reactions, but those happened in fewer participants.

Most common adverse reactions during the study

	Vial and syringe (out of 103 participants)	Accessorized pre-filled syringe (out of 105 participants)	Auto-injector (out of 106 participants)
Common cold	4.9% (5)	6.7% (7)	4.7% (5)
Headache	3.9% (4)	4.8% (5)	5.7% (6)
Pain in the mouth or throat	1.9% (2)	1.9% (2)	0.0% (0)
Dizziness	0.0% (0)	2.9% (3)	0.9% (1)
Nausea	1.0% (1)	1.0% (1)	0.9% (1)
Restlessness	1.0% (1)	1.0% (1)	0.0% (0)
Skin rash	0.0% (0)	1.0% (1)	0.9% (1)

How has this study helped patients and researchers?

This study helped researchers learn about the levels of tezepelumab in the blood when the drug is injected 1 time by different methods.

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 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 **"NCT03989544"** into the search box, and click **"Search"**.
- http://www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2018-004425-83"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5180C00012"** into the search box, and click **"Find a Study"**.

Full Trial Title: An Open Label, Randomized, Parallel Group Study to Evaluate the Pharmacokinetics of Tezepelumab Administered Subcutaneously via an Accessorized Pre-Filled Syringe (APFS) or Autoinjector (AI) Compared with Vial-And-Syringe in Healthy Adult Subjects (PATH-BRIDGE)

AstraZeneca AB Protocol Number: D5180C00012

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.

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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