AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Treatment Studied: Tezepelumab

Study Purpose: A study to find out about tezepelumab given through 2 different injection devices in participants with severe asthma

Protocol Number: D5180C00011

Thank you!

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

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

AstraZeneca AB sponsored this study and believes it is important to share the results of the study with the participants, their caregivers, 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 to find out if there is a better way to give a treatment for asthma, by giving it at home. The treatment is called tezepelumab. Before a treatment can be approved for people to take, researchers do clinical studies to find out how it works and how safe it is.

What treatments did the participants take?

The participants in this study got tezepelumab through a needle under the skin, also called an injection. They got tezepelumab through 1 of 2 different injection devices. These were called the accessorized pre-filled syringe, and an autoinjector.

What were the results of the study?

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

> How many participants had successful tezepelumab injections?

The researchers found that:

- 91.7% of the participants who got tezepelumab through the accessorized pre-filled syringe had successful injections. This was 100 out of 109 participants.
- 92.4% of the participants who got tezepelumab through the autoinjector had successful injections. This was 97 out of 105 participants.

> Did the participants feel that tezepelumab helped them control their asthma?

Yes. Overall, the researchers found that the participants felt that their asthma was more controlled after getting tezepelumab compared to before they started the study.

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

There were 2.8% of participants who had medical problems that the study doctors thought might be related to the study drug during the study. The most common medical problem was pain at the site of an injection. 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 can also be found on those websites.

Who took part in the study?

The researchers asked for the help of males and females with severe asthma. The participants in this study were 12 to 78 years old when they joined. The participants all had severe asthma.

The study included 216 participants in Canada, Japan, Poland, and the United States.

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 it works and how safe it is.

In this study, the researchers wanted to learn about 2 different devices to inject tezepelumab at the study site and at home in a large number of participants with severe asthma. They also wanted to find out if the participants had any medical problems during the study.

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. In this study, the researchers wanted to find out how well the participants or their caregivers or study doctors could inject tezepelumab using 2 different devices.

What was the purpose of this study?

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

- How many participants had successful tezepelumab injections?
- Did the participants feel that tezepelumab helped them control their asthma?
- 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 with asthma.

What treatments did the participants take?

This was an "open-label" study. This means that all of the participants, their caregivers, the researchers, study doctors, and other study staff knew that all the participants were getting tezepelumab. They also knew which injection device each participant was using.

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 dose of tezepelumab through 1 of 2 different injection devices. The participants got some of these injections from the study staff at the study site. The participants or their caregivers also did some of these injections themselves at home and at the study site.

There were 2 groups of participants. The first group 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 pre-filled syringe". Doctors use accessorized syringes to increase the safety of a syringe and reduce the chance of injury.

The second group of participants got an injection through an "autoinjector". Autoinjectors are devices that deliver injections by a button push or by pressing the device against the injection site.

A computer program was used to randomly choose the injection device that each participant used. This helped make sure the groups were chosen fairly. The researchers did this so that comparing the results of each injection device was as accurate as possible.

The chart below shows the treatments the participants got.

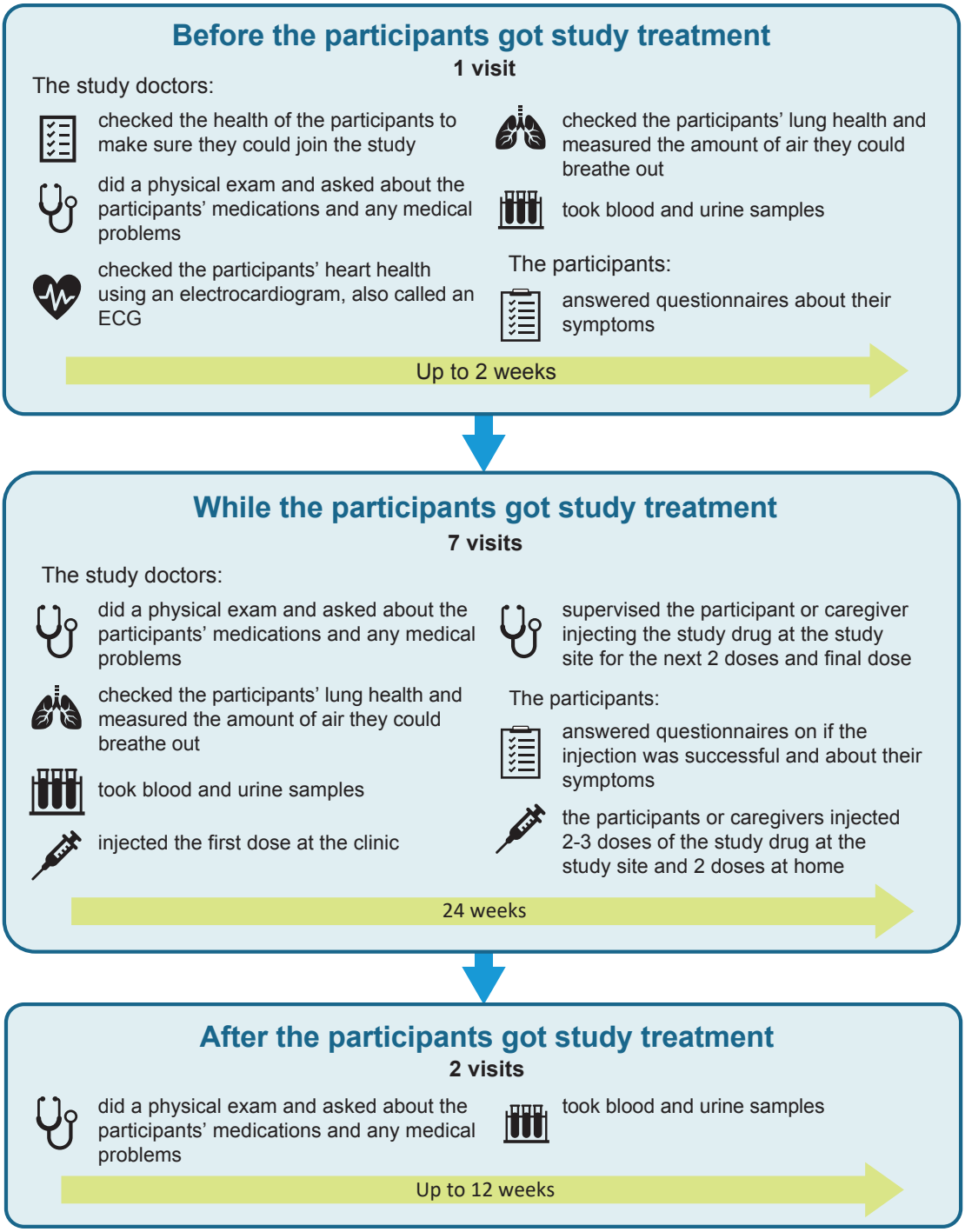
	Accessorized pre-filled syringe	Autoinjector
	• 111 participants	• 105 participants
	• Tezepelumab through the accessorized pre-filled syringe • 2 out of 6 injections were given at home	• Tezepelumab through the autoinjector • 2 out of 6 injections were given at home
	• 210 milligrams of tezepelumab every 4 weeks for a total of 6 doses	• 210 milligrams of tezepelumab every 4 weeks for a total of 6 doses

What happened during the study?

Each participant was in the study for about 9 months. But, the entire study took just over 1 year to finish.

The study started in May 2019 and ended in June 2020.

The chart below shows what happened during the study.



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 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.

There were 2 participants who did not get all of their injections. So, the results below include information for 214 out of 216 participants.

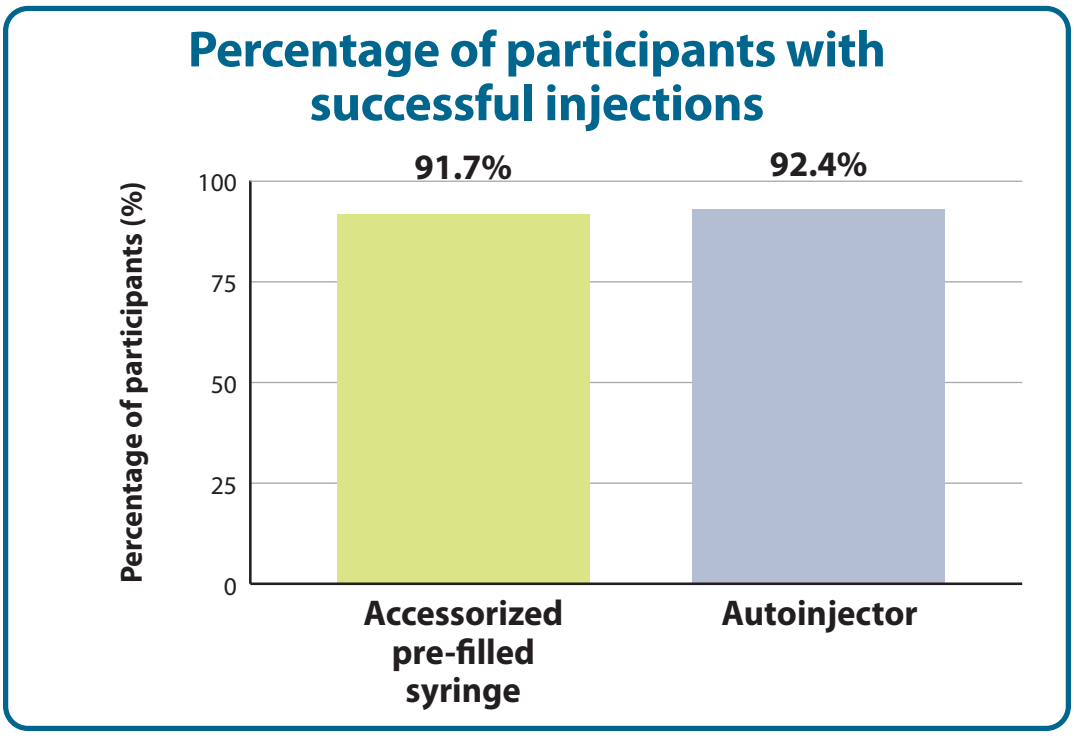
How many participants had successful tezepelumab injections?

To answer this question, the researchers calculated the percentage of participants who had successful tezepelumab injections over 20 weeks of getting the study drug. This included injections given by the study doctors, the participants' caregivers, or the participants themselves. After each injection, the participants filled out a questionnaire about whether the injection was successful. The participants returned the devices to the study site after use. The researchers looked at the devices and the questionnaires to decide whether the injections were successful. The researchers compared the results for the 2 injection devices.

The researchers found that:

- 91.7% of the participants who got tezepelumab through the accessorized pre-filled syringe had successful injections. This was 100 out of 109 participants.
- 92.4% of the participants who got tezepelumab through the autoinjector had successful injections. This was 97 out of 105 participants.

The graph below shows these results.



Did the participants feel that tezepelumab helped them control their asthma?

Yes. Overall, the researchers found that the participants felt that their asthma was more controlled after getting tezepelumab compared to before they started the study.

To answer this question, the study doctors asked the participants to answer a questionnaire about their asthma symptoms. The questionnaire is called the Asthma Control Questionnaire-6, also called ACQ-6. The participants received scores from 0 to 5 based on their responses. A lower score on the ACQ-6 means asthma symptoms are well controlled. From these scores, the researchers calculated the percentage of participants whose asthma was well controlled. They compared the results for each injection device from before and after 24 weeks of treatment.

At the start of the study, the percentage of participants who had well controlled asthma as measured on the ACQ-6 was:

- 1.8% of the participants who got tezepelumab through the accessorized pre-filled syringe. This was 2 out of 111 participants.
- 1.0% of the participants who got tezepelumab through the autoinjector. This was 1 out of 105 participants.

After 24 weeks of taking tezepelumab, the percentage of participants who had well controlled asthma was:

- 34.9% of the participants who got tezepelumab through the accessorized pre-filled syringe. This was 38 out of 109 participants.
- 36.2% of the participants who got tezepelumab through the autoinjector. This was 38 out of 105 participants.

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 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 the study drug.

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 2.8% of participants who had adverse reactions during this study. This was 6 out of 216 participants.

- None of the participants who got tezepelumab through the accessorized pre-filled syringe had an adverse reaction.
- 5.7% of the participants who got tezepelumab through the autoinjector had adverse reactions. This was 6 out of 105 participants.

None of the participants had serious adverse reactions.

None of the participants stopped taking study treatment due to adverse reactions.

What adverse reactions happened during this study?

The most common adverse reaction was pain at the site of an injection.

The table below shows the adverse reactions that happened during this study. Some participants may have had more than 1 adverse reaction.

Adverse reactions during this study

Adverse reaction	Accessorized pre-filled syringe (out of 111 participants)	Autoinjector (out of 105 participants)
Injection site pain	0.0% (0)	2.9% (3)
Injection site redness	0.0% (0)	1.9% (2)
Injection site swelling	0.0% (0)	1.9% (2)
Injection site bruising	0.0% (0)	1.0% (1)
Injection site raised swelling	0.0% (0)	1.0% (1)
Injection site itching	0.0% (0)	1.0% (1)

How has this study helped patients and researchers?

This study helped researchers learn more about using 2 different devices to inject tezepelumab in participants with severe 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 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 **"NCT03968978"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2018-004588-30"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D5180C00011"** into the search box, and click **"Find a Study"**.

Full Study Title: A Multicentre, Randomised, Open-label, Parallel-group, Functionality, and Performance Study of an Accessorised Pre-filled Syringe and Autoinjector with Home-administered Subcutaneous Tezepelumab in Adolescent and Adult Subjects with Severe Asthma (PATH-HOME)

AstraZeneca AB Protocol Number: D5180C00011

National Clinical Trials number: NCT03968978

EudraCT number: 2018-004588-30

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!

Participants in clinical studies 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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