Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD9567

Study Title: A study to learn if AZD9567 helps people with rheumatoid arthritis

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD9567. All of the participants helped researchers learn more about AZD9567 to help people who have rheumatoid arthritis, also called RA.

AstraZeneca AB sponsored this study and thinks it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their 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 rheumatoid arthritis, also called RA. Before a drug 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 took AZD9567 and a placebo that looked like prednisolone, or they took prednisolone and a placebo that looked like AZD9567. Prednisolone is a steroid treatment that has already been approved to treat RA. A placebo looks like a drug but does not have any medicine in it.

What were the results of the study?

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

- **Did AZD9567 help the participants manage their RA symptoms?**
  To answer this question, the researchers studied the severity of the participants' RA before and after they took study treatment. They found that in both treatment groups, there was a decrease in the severity of the participants' RA. The researchers considered this decrease to be similar for both groups.
- **What medical problems happened during the study?**
  There were 42.9% of participants in the overall study who had medical problems that the study doctors thought might be related to the study treatments. The most common medical problems were dry mouth, feeling hot, pain in the upper stomach area, and increased appetite.

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 men and women who have RA. The participants were 29 to 79 years old when they joined.

The study included 21 participants in the Netherlands and Sweden.

Why was the research needed?

Researchers are looking for a better way to treat RA. Before a drug 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 find out if AZD9567 works in a small number of participants who have RA. They also wanted to find out if the participants had any medical problems during the study.

RA is a condition in which a person's immune system does not work correctly. In RA, the immune system attacks the body's tissues, joints, and organs. This leads to pain and swelling in the body.

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

The study drug, AZD9567, is being developed to reduce inflammation in people who have diseases such as RA. In this study, the researchers wanted to learn if AZD9567 helped the participants manage their RA symptoms. They also wanted to compare AZD9567 to a drug called prednisolone, which is a steroid treatment that has already been approved to treat RA.

What was the purpose of this study?

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

- Did AZD9567 help the participants manage their RA symptoms?
- What medical problems happened during the study?

The answers to these questions are important to know before other studies can be done that help find out if AZD9567 helps improve the health of people who have RA.

What treatments did the participants take?

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 taking. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. When the study ended, the research sponsor found out which treatment the participants took so they could create a report of the study results.

In this study, the participants took either AZD9567 and a placebo that looked like prednisolone, or they took prednisolone and a placebo that looked like AZD9567. 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 take the drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant took. 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.

AZD9567 and the placebo that looked like AZD9567 were taken as liquids by mouth. Prednisolone and the placebo that looked like prednisolone were taken as pills by mouth. The treatment doses were measured in milligrams, also called mg. The chart below shows the treatment the participants took.

	40 mg AZD9567 and prednisolone placebo (11 participants)	**20 mg prednisolone and AZD9567 placebo (10 participants)**
How did the participants take study treatment?	AZD9567: as a liquid by mouth Prednisolone placebo: as pills by mouth	Prednisolone: as pills by mouth AZD9567 placebo: as a liquid by mouth
How often did the participants take study treatment?	Once a day for 2 weeks	Once a day for 2 weeks

What happened during the study?

The participants were in the study for up to about 1 month. But, the entire study took about 2 years to finish. The study started in January 2018 and ended in November 2019.

Before the participants took treatment, they visited their study site 1 time over the course of about 1 week. During this time, the study doctors checked to make sure the participants could join the study. The study doctors:

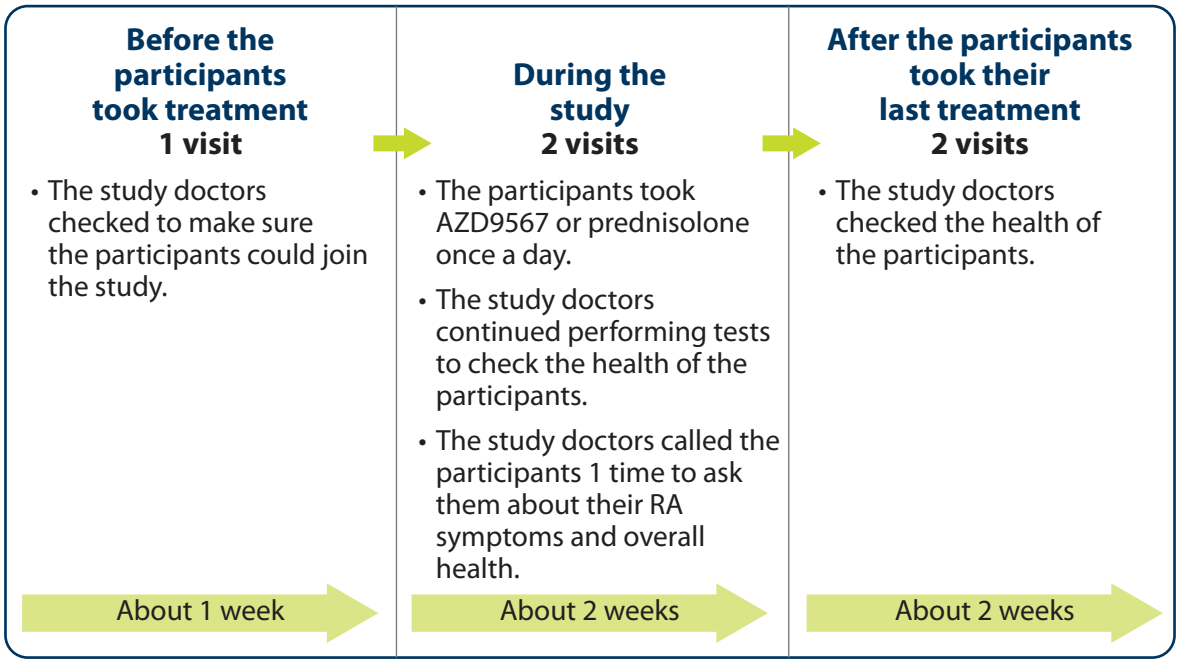
- did a physical examination and checked the participants' vital signs
- took blood and urine samples
- gave the participants surveys that asked them about their RA symptoms
- checked the participants' heart health using an electrocardiogram, also called an ECG
- asked the participants about their medical history, how they were feeling, and what medicines they were taking

During the study, the participants visited their study site 2 times over the course of about 2 weeks. During this time, they took either 40 mg of AZD9567 or 20 mg of prednisolone 1 time each day. The study doctors also called the participants 1 time to ask them about their RA symptoms and overall health.

Throughout the study, the study doctors continued performing tests to check the health of the participants and gave the participants surveys asking them about their RA symptoms.

After the participants took their last treatment, they visited their study site 2 times over the course of about 2 weeks. At these visits, the study doctors checked the participants' overall health and asked them about their RA symptoms.

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. A full list of the questions the 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.

Did AZD9567 help the participants manage their RA symptoms?

To answer this question, the researchers studied the change in the severity of the participants' RA. They did this by looking at the participants' test and survey results before and after they took study treatment. Then, the researchers compared the results of the participants who took AZD9567 with the results of the participants who took prednisolone.

The researchers kept track of the severity of the participants' RA by using the Disease Activity Score, also called DAS. The DAS is a score based on the results of several tests and measurements. A higher score means more severe RA.

The researchers used the following information to calculate the participants' DAS:

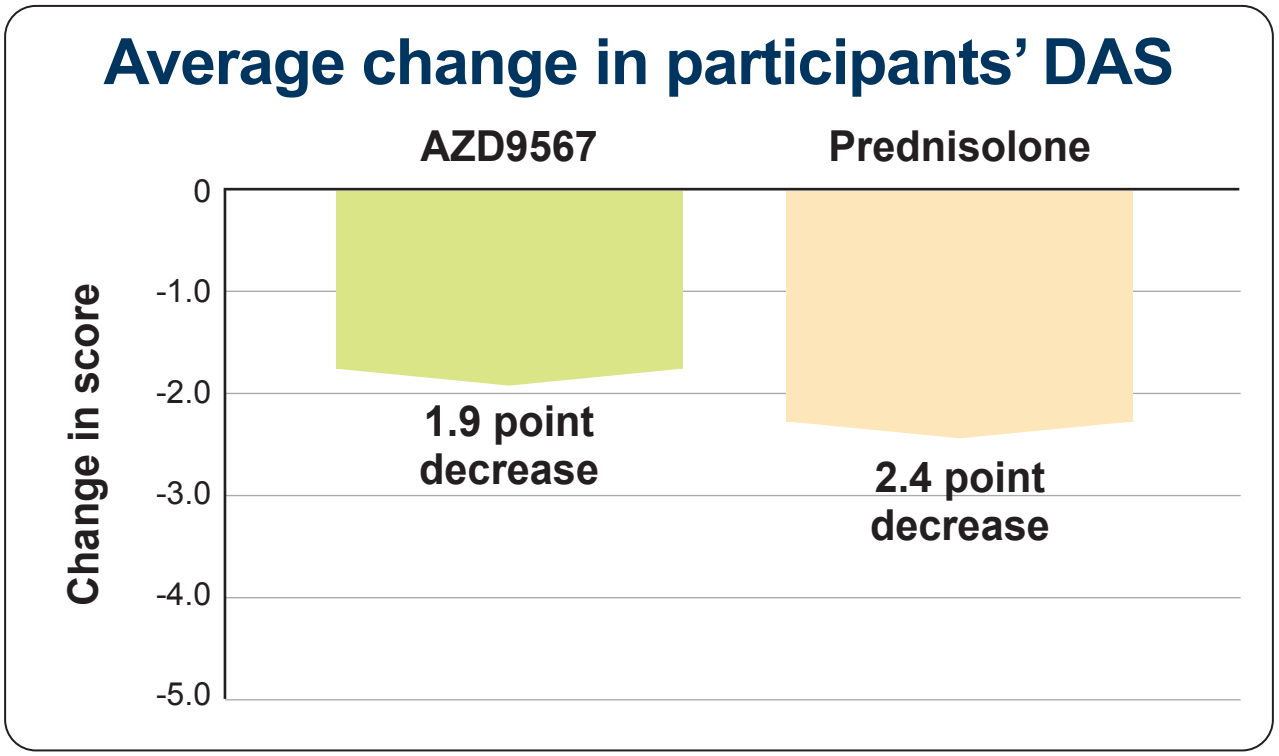
- number of swollen and tender joints
- amount of swelling in the body
- surveys asking the participants to rate how RA was affecting their daily activities

After the participants took study treatment for 2 weeks, the researchers found that the participants who took AZD9567 and the participants who took prednisolone had a decrease in their DAS. The researchers considered this decrease to be similar for both groups.

After the participants took study treatment for 2 weeks, the researchers found that:

- The participants who took AZD9567 had an average decrease in their DAS of 1.9 points.
- The participants who took prednisolone had an average decrease in their DAS of 2.4 points.

The figure below shows these results.



The researchers also gave the participants surveys throughout the study asking them to rate their overall pain and their pain from RA. After the 2-week treatment period, the participants who took AZD9567 and the participants who took prednisolone reported a decrease in their overall pain and their pain from RA. The researchers considered this decrease to be similar for both groups.

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.

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 42.9% of participants in the overall study who had adverse reactions. This was 9 out of 21 participants.

The table below shows how many participants had adverse reactions.

Adverse reactions during the study

	40 mg AZD9567 (out of 11 participants)	20 mg prednisolone (out of 10 participants)
How many participants had adverse reactions?	54.5% (6)	30.0% (3)
How many participants had serious adverse reactions?	9.1% (1)	0.0% (0)
How many participants left this study due to adverse reactions?	0.0% (0)	0.0% (0)

What serious adverse reactions happened during this study?

There were 4.8% of participants in the overall study who had serious adverse reactions. This was 1 out of 21 participants. This participant was in the AZD9567 group and had the serious adverse reaction of depression.

None of the participants died during this study.

What adverse reactions happened during this study?

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

Most common adverse reactions during the study

Adverse reaction	40 mg AZD9567 (out of 11 participants)	20 mg prednisolone (out of 10 participants)
Dry mouth	18.2% (2)	0.0% (0)
Feeling hot	18.2% (2)	0.0% (0)
Pain in the upper stomach area	18.2% (2)	0.0% (0)
Increased appetite	9.1% (1)	10.0% (1)

How has this study helped patients and researchers?

This study helped researchers learn if AZD9567 helps people who have RA to manage their symptoms.

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 AZD9567 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 **"NCT03368235"** into the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6470C00003"** into the search box, and click **"Find a Study"**.

Full Trial Title: A Phase 2a, Randomised, Double-blind, Parallel Study to Assess the Efficacy, Safety and Tolerability of AZD9567 compared to Prednisolone 20 mg in patients with active Rheumatoid Arthritis (RA)

AstraZeneca AB Protocol Number: D6470C00003

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.

CISCRP
One Liberty Square, Suite 1100 • Boston, MA 02109
1-877-MED-HERO • www.ciscrp.org