Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca AB

Drug Studied: AZD9567

Study Title: A study to learn about the safety of different AZD9567 doses in healthy participants

Thank you!

Thank you to the participants who took part in the clinical study for the study drug AZD9567. 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 doctor or staff at your study site.

What is happening with the study now?

The study started in May 2016 and ended in September 2017.

The study included 77 participants in Germany and the United Kingdom.

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 patients with inflammatory diseases such as rheumatoid arthritis, also called RA. Before a drug can be approved for patients to take, researchers do clinical studies to find out if it works and how safe it is.

RA is a condition in which a person's immune system does not work correctly. This can cause the immune system to attack the body's tissues, joints, and organs. This can lead to pain and swelling in the body.

The study drug, AZD9567, is being developed to treat patients with RA. In this study, the researchers wanted to learn more about different AZD9567 doses and if they are safe to take. They also wanted to compare AZD9567 to a drug called prednisolone that is currently used to treat RA.

There are treatments available for RA, such as prednisolone, but these treatments can cause medical problems. So, researchers are looking for new ways to treat RA.

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

- Did the safety results change in participants who took AZD9567?
- 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 that help find out if AZD9567 improves the health of people with RA.

The researchers asked for the help of healthy men and women, as well as pre-diabetic men and women. Pre-diabetic means that the person has high blood sugar levels, but the levels are not high enough for that person to be considered diabetic. The researchers included pre-diabetic participants because they wanted to learn if the study treatments affected blood sugar levels in the body. Everyone in the study was 18 to 60 years old when they joined.

What kind of study was this?

This was a “single-blind” study. This means the researchers knew what the participants were taking but the participants did not.

In this study, there were 2 different treatments: the study drug AZD9567 and a drug called prednisolone. The participants in this study took either prednisolone and a placebo that looked like AZD9567 or AZD9567 and a placebo that looked like prednisolone. 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.

Prednisolone and the placebo that looked like it were taken in pill form by mouth. AZD9567 and the placebo that looked like it were taken in liquid form by mouth. Each treatment dose was measured in milligrams, also called mg.

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.

What happened during the study?

Before treatment, the study doctors checked to make sure the participants could join the study. The study doctors:

- did a physical examination
- took blood and urine samples
- checked the heart health of the participants 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 treatment, the participants stayed at their study site for 1 week. During this time, the participants took 1 of the below 8 treatments once a day for 5 days. The treatments were taken without food:

Group	Number of participants	Treatment
1	13	5 mg of prednisolone + placebo
2	16	20 mg of prednisolone + placebo
3	13	40 mg of prednisolone + placebo
4	7	10 mg of AZD9567 + placebo
5	7	20 mg of AZD9567 + placebo
6	7	40 mg of AZD9567 + placebo
7	7	80 mg of AZD9567 + placebo
8	7	125 mg of AZD9567 + placebo

Throughout the study, the doctors continued taking blood and urine samples from the participants and checking their overall health.

After treatment, the participants visited their study site 1 time. During this visit, the study doctors took blood and urine samples, checked the participants' overall health, and asked the participants how they were feeling.

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 changes.

The websites listed at the end of this summary may have a full report of the study results.

Did the safety results change in participants who took AZD9567?

No. Overall, the researchers found that the safety results for the participants who took AZD9567 did not change during the study.

To answer this question, the researchers did tests and took measurements throughout the study. The researchers:

- took blood and urine samples
- did ECGs
- did physical examinations
- studied vital signs

The researchers did these tests and measurements before the participants took the study treatment, and throughout the study. Overall, the researchers did not find a meaningful change in these measurements throughout the study.

What medical problems did the participants have during the study?

This section is a summary of the medical problems the participants had during the study. These medical problems are called “adverse events”. Adverse events are considered “serious” when they are life-threatening, cause lasting problems, or require hospital care.

Adverse events may or may not be caused by the study drug. A lot of research is needed to know whether a drug causes an adverse event.

The websites listed at the end of this summary may have more information about the adverse events that happened during this study.

How many participants had serious adverse events?

None of the participants had serious adverse events during the study.

None of the participants died during the study.

How many participants had adverse events?

There were 29.9% of participants who had adverse events during the study. This was 23 out of 77 participants.

There were 1.3% of participants who stopped study treatment because of an adverse event they had during the study. This was 1 out of 77 participants. This adverse event was a stomach flu, and the study doctors did not think it was related to the study treatment.

The table below shows how many participants had adverse events during the study.

Adverse events during the study

	How many participants had adverse events during the study?	How many participants had serious adverse events during the study?	How many participants stopped treatment because of adverse events?
Group 1 (out of 13 participants)	23.1% (3)	0.0% (0)	0.0% (0)
Group 2 (out of 16 participants)	31.3% (5)	0.0% (0)	6.3% (1)
Group 3 (out of 13 participants)	46.2% (6)	0.0% (0)	0.0% (0)
Group 4 (out of 7 participants)	28.6% (2)	0.0% (0)	0.0% (0)
Group 5 (out of 7 participants)	0.0% (0)	0.0% (0)	0.0% (0)
Group 6 (out of 7 participants)	57.1% (4)	0.0% (0)	0.0% (0)
Group 7 (out of 7 participants)	14.3% (1)	0.0% (0)	0.0% (0)
Group 8 (out of 7 participants)	28.6% (2)	0.0% (0)	0.0% (0)

What adverse events did the participants have?

The most common adverse event during the study was headache. The tables below show the adverse events that happened in at least 2 participants during the study. There were other adverse events, but these happened in fewer participants. Some of the participants had more than 1 adverse event.

Adverse events during the study (prednisolone groups)

	Group 1 (out of 13 participants)	Group 2 (out of 16 participants)	Group 3 (out of 13 participants)
Headache	0.0% (0)	6.3% (1)	38.5% (5)
General pain in the body	7.7% (1)	0.0% (0)	0.0% (0)
Nausea	0.0% (0)	6.3% (1)	0.0% (0)
Tingling, burning, or numb sensation on skin	0.0% (0)	6.3% (1)	0.0% (0)
Dizziness	0.0% (0)	0.0% (0)	7.7% (1)
Hoarse voice	0.0% (0)	0.0% (0)	7.7% (1)
Sudden urge to urinate	0.0% (0)	0.0% (0)	0.0% (0)

Adverse events during the study (AZD9567 groups)

	Group 4 (out of 7 participants)	Group 5 (out of 7 participants)	Group 6 (out of 7 participants)	Group 7 (out of 7 participants)	Group 8 (out of 7 participants)
Headache	0.0% (0)	0.0% (0)	28.6% (2)	14.3% (1)	28.6% (2)
General pain in the body	0.0% (0)	0.0% (0)	14.3% (1)	0.0% (0)	0.0% (0)
Nausea	0.0% (0)	0.0% (0)	14.3% (1)	0.0% (0)	0.0% (0)
Tingling, burning, or numb sensation on skin	14.3% (1)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Dizziness	0.0% (0)	0.0% (0)	14.3% (1)	0.0% (0)	0.0% (0)
Hoarse voice	0.0% (0)	0.0% (0)	14.3% (1)	0.0% (0)	0.0% (0)
Sudden urge to urinate	28.6% (2)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of different AZD9567 doses in healthy participants and pre-diabetic participants.

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.

A clinical study with AZD9567 in patients with RA is ongoing.

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 "**NCT02760316**" into the search box, and click "**Search**".
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2015-005815-34"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6470C00002"** into the search box and click **"Find a Study"**.

Full Trial Title: A Phase I, Randomised, Single-blind Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Multiple Ascending Doses of AZD9567 in Healthy Volunteers Using Prednisolone as Positive Control

AstraZeneca Protocol Number: D6470C00002

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.

CISCRP
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