AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Treatment Studied: AZD9567

Study Purpose: This study was done to learn how AZD9567 works compared with prednisolone in participants with type 2 diabetes

Protocol Number: D6470C00005

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 with type 2 diabetes who also take treatment for inflammation.

AstraZeneca AB sponsored this study and believes it is important to share the results of the study with you 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 for a better way to treat inflammation in people who have type 2 diabetes. 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 different combinations of AZD9567, prednisolone, and a placebo. A placebo looks like a drug but does not have any medicine in it.

What were the results of this study?

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

- **Did AZD9567 affect how much glucose got into the participants' blood compared to prednisolone?**

  Yes. Overall, the researchers found that taking AZD9567 **decreased** how much glucose got into the participants' blood compared with taking prednisolone. "Glucose" is also known as blood sugar.

- **What medical problems happened during this study?**

  There were 2.4% of participants who had medical problems that the study doctors thought might be related to the study treatments during the study. The only medical problem was having high levels of blood glucose.

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 also can be found on these websites.

Who took part in this study?

The researchers asked for the help of men and women with type 2 diabetes. The participants in this study were 50 to 75 years old when they joined.

The participants could join the study if they were:

- diagnosed with type 2 diabetes at least 6 months before they joined the study
- taking a type of treatment called metformin for at least 4 weeks before joining the study

The study included 46 participants in Germany.

Why was the research needed?

Researchers are looking for a better way to treat people who have type 2 diabetes who also need to take drugs to reduce inflammation in their body. 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 how much glucose is released into the blood after a meal with AZD9567 compared to prednisolene in a small number of participants with type 2 diabetes. They also wanted to find out if the participants had any medical problems during the study.

Type 2 diabetes can be caused by treatment for inflammatory diseases. In people with inflammatory diseases, type 2 diabetes occurs by mistake.

Inflammatory diseases can be treated with a type of drug called "steroids". Steroids are designed to decrease the activity of the immune system by reducing inflammation in the body. Prednisolone is a type of steroid.

But, when steroids are taken for a long time, they can cause "blood glucose levels" to rise higher than normal levels. Blood glucose levels show the amount of sugar in the blood. Increases in blood glucose levels can cause medical problems, such as type 2 diabetes, or make it worse for people who already have type 2 diabetes. Researchers are trying to find treatments that help reduce inflammation without increasing blood glucose levels.

The study drug, AZD9567, is being developed to try to reduce inflammation in people with inflammatory diseases, but works differently than steroids. Researchers want to find out if AZD9567 causes a smaller increase in blood glucose levels than steroids.

In this study, the researchers wanted to find out if taking AZD9567 affected how much glucose got into the participants' blood compared with taking prednisolone.

What was the purpose of this study?

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

- Did AZD9567 affect how much glucose got into the participants' blood compared to prednisolone?
- What medical problems happened during this study?

The answers to these questions are important to know before other studies can be done to find out if AZD9567 helps improve the health of people with type 2 diabetes.

What treatments did the participants take?

In this study, the participants took different combinations of AZD9567, prednisolone, and a placebo. 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.

This study had 3 treatment groups:

- Participants in **Group 1** took a **high dose** of AZD9567 and prednisolone
- Participants in **Group 2** took a **low dose** of AZD9567 and prednisolone
- Participants in **Group 3** took a **placebo** and a **very low dose** of prednisolone

Each group had 2 parts. During **Part 1**, the participants stayed at the study site for 6 days and took their treatment, called **"Treatment 1"**, for 3 days. Then, they stayed at home and took no treatments for 3 weeks. This was done so that the treatment could leave the participants' bodies before Part 2 of the study. During **Part 2**, the participants stayed at the study site for 6 days and took their second treatment, called **"Treatment 2"**, for 3 days.

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, or the order in which the participants took their study treatments. 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.

This was a "double placebo" study. This means that the participants took both a tablet and a liquid study treatment at the same time. One of these treatments was a placebo and the other was AZD9567, prednisolone, or a placebo. None of the participants, researchers, and study doctors knew whether the tablet or liquid was a placebo, or if both were a placebo.

A computer program was used to randomly choose the treatment group for each participant, as well as the order in which the participants took their study treatments. 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 dose of the study treatments was measured in milligrams, also known as "mg". The chart below shows the treatments the researchers planned to study.

	Group 1	Group 2	Group 3
	28 participants	9 participants	9 participants
	• 72 mg of AZD9567 as a liquid by mouth, together with placebo as a capsule by mouth • 40 mg of prednisolone as a capsule by mouth, together with placebo as a liquid by mouth	• 40 mg of AZD9567 as a liquid by mouth, together with placebo as a capsule by mouth • 20 mg of prednisolone as a capsule by mouth, together with placebo as a liquid by mouth	• 5 mg of prednisolone as a capsule by mouth, together with placebo as a liquid by mouth • Placebo as a capsule by mouth and as a liquid by mouth
	**During Part 1:** • Treatment 1 for 3 days **During Part 2, 3 weeks later:** • Treatment 2 for 3 days	**During Part 1:** • Treatment 1 for 3 days **During Part 2, 3 weeks later:** • Treatment 2 for 3 days	**During Part 1:** • Treatment 1 for 3 days **During Part 2, 3 weeks later:** • Treatment 2 for 3 days

What happened during this study?

The participants were in the study for up to 11 weeks. But, the entire study took over 6 months to finish.

The study started in November 2020 and ended in June 2021.

The chart below shows what happened during the study.

Before the participants got study treatment

1 visit

The study doctors:

- checked the health of the participants to make sure they could join the study
- did physical exams and asked about the participants' medications and any medical problems
- took blood and urine samples
- checked the participants' heart health using an electrocardiogram, also called an ECG
- checked if the participants had COVID-19

Up to 4 weeks

While the participants got study treatment

4 visits, including overnight visits

The study doctors:

- did physical exams and asked about the participants' medications and any medical problems
- took blood and urine samples
- checked the participants' heart health using an ECG
- checked if the participants had COVID-19

The participants:

- wore a device called a continuous glucose monitor that measured their blood glucose levels
- took their study treatments at the study site

Up to 6 weeks

After the participants got study treatment

1 visit

The study doctors:

- did physical exams and asked about the participants' medications and any medical problems
- took blood and urine samples
- checked the participants' heart health using an ECG
- checked if the participants had COVID-19

About 5 weeks after the last dose of study treatment

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. A full list of the questions that 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 take all of their doses of study treatment. The results from these participants were not counted.

Did AZD9567 affect how much glucose got into the participants' blood compared to prednisolone?

Yes. Overall, the researchers found that taking AZD9567 did affect how much glucose got into the participants' blood compared to taking prednisolone.

To answer this question, the researchers measured the average total blood glucose levels before treatment, and 4 hours after the participants ate a liquid meal replacement followed by their study treatment. They did this for both Treatment 1 and Treatment 2 for each group. The researchers then compared the average total amount of glucose that got into the participants' blood after they took AZD9567 or prednisolone.

In Group 1, overall, the researchers found that the average total blood glucose level was **lower** after the participants took AZD9567 compared with when they took prednisolone.

There were not enough participants in Group 2 and Group 3 for the researchers to know if taking AZD9567 or prednisolone, or taking prednisolone or placebo, affected how much glucose got into the participants' blood.

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 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 AZD9567 and prednisolone.

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.

This section does not include information from the 2 participants who did not take all of their doses of study treatment. This was 1 participant from Group 1, and 1 participant from Group 2.

Did any adverse reactions happen during this study?

	Group 1 (out of 27 participants)	**Group 2** (out of 8 participants)	**Group 3** (out of 9 participants)
How many participants had adverse reactions?	3.7% (1)	None	None
How many participants had serious adverse reactions?	None	None	None
How many participants stopped taking study treatment due to adverse reactions?	None	None	None

What serious adverse reactions happened during this study?

None of the participants had any serious adverse reactions.

What adverse reactions happened during this study?

The only adverse reaction that happened during the study was having high levels of blood glucose.

This happened in:

- 3.7% participants from Group 1. This was 1 out of 27 participants
- No participants from Group 2
- No participants from Group 3

How has this study helped patients and researchers?

This study helped researchers learn more about whether taking AZD9567 affected how much glucose got into the participants' blood compared with taking prednisolone.

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 and prednisolone are not 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 **"NCT04556760"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2020-000931-35"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D6470C00005"** into the search box and click **"Find a Study"**.

Full Study Title: Phase IIa, Randomised, Double Blind, Multi-centre Study to Assess the Effect on Glucose Homeostasis of Two Dose Levels of AZD9567, Compared to Prednisolone, in Adults with Type 2 Diabetes

AstraZeneca AB Protocol Number: D6470C00005

National Clinical Trials Number: NCT04556760

EudraCT Number: 2020-000931-35

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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