

Clinical Trial RESULTS



Research Sponsor: AstraZeneca AB

Drugs Studied: AZD9567

National Clinical Trial #: NCT02512575

Protocol #: D6470C00001

Study Date: November 2015 to September 2016

Short Study Title: A study in healthy participants to see how AZD9567 acts in the body and how safe it is to take

Thank you!

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and discover new medical treatments.

Thank you for taking part in the clinical study for the drug AZD9567. This drug is being developed to treat inflammatory diseases, or diseases that cause swelling within the body. One of these diseases is called rheumatoid arthritis, or RA. RA can affect the joints, causing swelling, pain, and stiffness. You and all of the participants helped researchers learn how AZD9567 acts in the body and if the drug causes medical problems.

AstraZeneca AB, the sponsor of this study, thanks you for your help and thinks it is important for you to know the results of your study. An independent non-profit organization called CISCRP prepared this summary of the study results for you with the help of a medical writing organization. We hope it helps you understand and feel proud of your important role in medical research. If you have questions about the results, please speak with the doctor or staff at your study site.

What has happened since my study ended?

Your study started in November 2015 and ended in September 2016. It included 72 participants at 1 study site in Germany. When the study ended, the sponsor reviewed the data and created a report of the results. This is a summary of that report.

Why was the research needed?

Before a new drug can be approved, research must be done to show that it is safe and effective. The first step in studying a new drug is to test it in healthy people, or in people without any serious health problems.

The study drug, AZD9567, is being developed to treat inflammatory diseases like RA. RA can affect the joints, causing swelling, pain, and stiffness.

Researchers wanted to see how AZD9567 acted in the body and if it caused any medical problems. In the study, researchers compared AZD9567 to a placebo and a steroid. A placebo looks like the study drug but contains no real medicine in it. The type of steroid used in this study is a medicine that is commonly used to treat inflammatory diseases like RA. Steroids, however, can have negative effects on the body's sugar levels and cause them to increase.

Researchers wanted to know:

- How did AZD9567 act in the body?
- How did AZD9567 and the steroid each affect participants' blood sugar levels?
- What medical problems did participants have after getting AZD9567?

What kind of study was this?

Your study was a "single-blind" study. In this study, this means that some study staff knew what study drug each participant took, but the participants did not. Some studies are done this way because knowing what treatment each participant is getting can affect the results of the study. This way, the results are looked at fairly.

In this study, all participants got AZD9567, a steroid, or a placebo. The researchers randomly separated participants into different treatment groups.

Your study included healthy men who were 19 to 55 years old.

What happened during the study?

You and other participants were in the study for up to 16 weeks.

First, to see if you could join the study, researchers did a physical exam, which included checking your height, weight, and temperature. They also tested samples of your urine and blood to check your overall health, and did an electrocardiogram, or ECG, to check your heart health. Researchers also asked about your medical history, how you were feeling, and what medicines you were taking.

Once you joined the study, you were randomly assigned to get one of the 3 treatments listed below.

During the study, 64 participants were randomly put into 8 groups. Within these 8 groups, participants were randomly assigned to take either AZD9567 or a placebo. The last 8 participants were put into a ninth group and were randomly assigned to take either a steroid or a placebo. Most of the participants in the study got AZD9567, so all participants did not have an equal chance of getting AZD9567, the steroid, or a placebo. The study's treatment design is listed below:

- 48 participants got AZD9567 in liquid form through the mouth. They got the study drug in doses of 2, 10, 20, 40, 80, 100, 125, or 155 milligrams, or mg.
- 16 participants got the placebo in liquid form through the mouth.
- 2 participants got the placebo in pill form.
- 6 participants got 60 mg of the steroid in pill form.

Before treatment, all participants stayed at the study center for 2 days. During treatment, all participants got their doses on the first day of the study, which was called Day 1. They stayed at the study center for the 2 days of the treatment period, Day 1 and Day 2, and left on Day 3. So all participants stayed at the study center for a total of 4 days. Participants came back to the study center for 1 follow-up visit 7 to 10 days after treatment.

There were 9 groups of participants in this study, and each group had 8 participants.

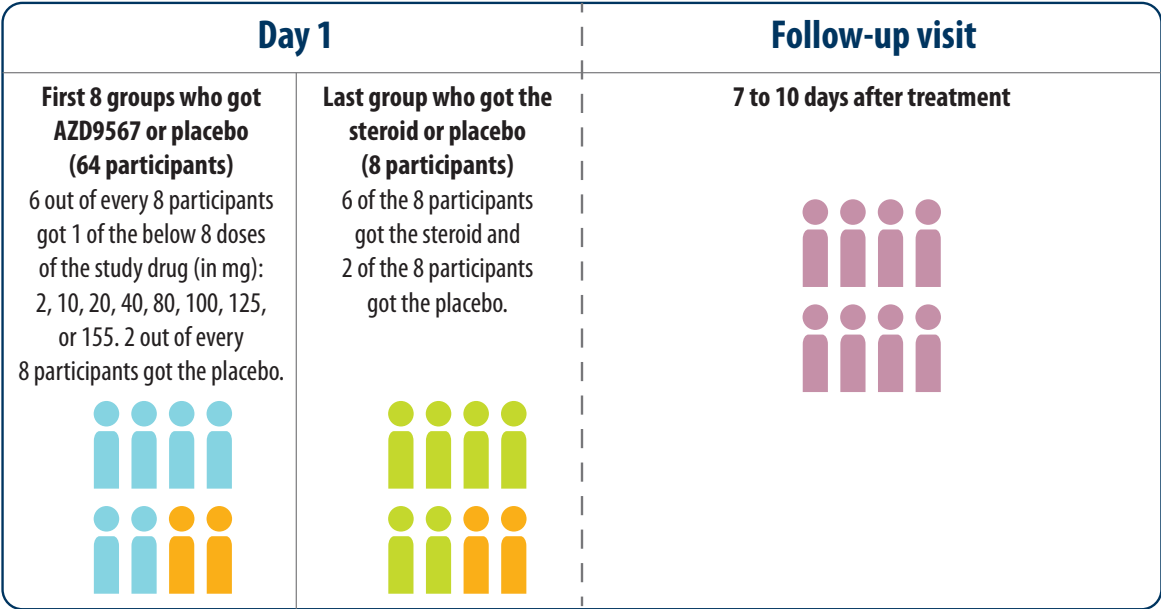
In the first 8 groups, 6 out of every 8 participants got AZD9567 and 2 out of every 8 participants got the placebo. The doses of AZD9567 per group are listed below:

- Group 1 participants got 2 mg of AZD9567
- Group 2 participants got 10 mg of AZD9567
- Group 3 participants got 20 mg of AZD9567
- Group 4 participants got 40 mg of AZD9567
- Group 5 participants got 80 mg of AZD9567
- Group 6 participants got 100 mg of AZD9567
- Group 7 participants got 125 mg of AZD9567
- Group 8 participants got 155 mg of AZD9567

In the ninth group, 6 out of the 8 participants got the steroid and 2 of the 8 participants got the placebo.

In the first 8 groups, both the participants who got AZD9567 and the participants who got the placebo took their treatments in liquid form through the mouth. In the ninth group, both the participants who got the steroid and the participants who got the placebo took their treatments in the form of a pill. All participants were given their treatments without food.

The figure below shows how the study was done.



During the study, study doctors checked each participant’s blood pressure, pulse rate, and temperature. They also tested participants’ blood and urine to make sure the participants were still healthy. Finally, study doctors checked participants’ hearts using an electrocardiogram, or ECG. Study doctors also asked participants how they were feeling.

After the treatments were over, participants returned to the study center for a follow-up visit 7 to 10 days after treatment. During this visit, study doctors took additional blood and urine samples, and asked participants how they were feeling. Researchers also did an ECG to check participants’ heart health, and did a full physical examination.

What were the study results?

Below is a summary of the results of some of the questions the researchers asked during this study. It is important to know that researchers look at the results of many studies to decide which medicines work best and are safest for patients. Further clinical studies with AZD9567 are ongoing.

How did AZD9567 act in the body?

Researchers wanted to see how the study drug acted in the body. They wanted to know:

- The average amount of AZD9567 in the blood
- The highest amount of AZD9567 in the blood
- How long it took for AZD9567 to reach its highest amount in the blood

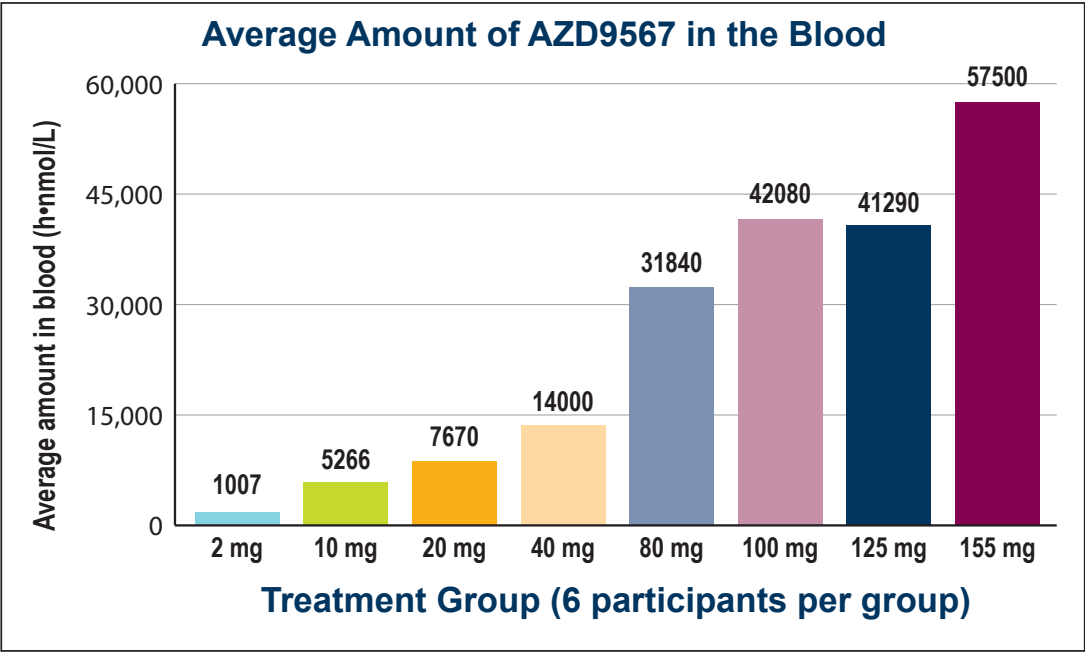
Average amount of AZD9567 in the blood

Researchers measured the average amount of AZD9567 in participants’ blood in nanomole hours per liter of blood (h•nmol/L). This is a widely accepted scientific unit of measurement.

After being swallowed by participants, AZD9567 was taken up quickly into the blood. This process took about 1 hour.

AZD9567 also disappeared quickly from the blood. Roughly 5 hours after participants got AZD9567, the original amount of the study drug in participants’ blood was cut in half.

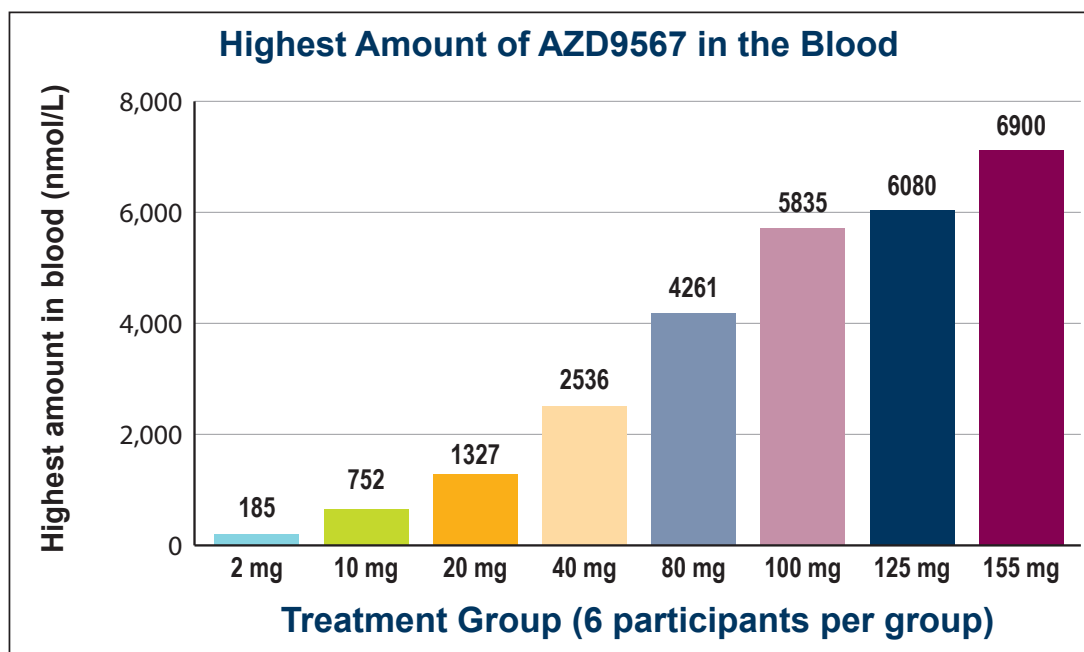
The figure below shows this amount for the 8 AZD9567 treatment groups.



Highest amount of AZD9567 in the blood

Researchers measured the highest amount of AZD9567 in participants’ blood in nanomoles per liter of blood (nmol/L). This is a widely accepted scientific unit of measurement.

The figure below shows this amount for the 8 AZD9567 treatment groups.



How long it took for AZD9567 to reach its highest amount in the blood

Researchers measured how long it took for AZD9567 to reach its highest amount in participants' blood.

Overall, researchers found the following:

- Generally, higher doses of AZD9567 led to participants having larger average amounts and larger highest amounts of the study drug in their blood.
- Generally, it took about an hour for the study drug to reach its highest amount in the blood.

How did AZD9567 and the steroid each affect participants' blood sugar levels?

Researchers found the following:

- Participants who got 100, 125, and 155 mg of AZD9567 had higher average sugar levels in their blood than participants who got the placebo.
- Participants who got the steroid also had higher average sugar levels in their blood than participants who got the placebo.
- Participants who got 2, 10, 20, 40, and 80 mg of AZD9567 did not see any effect on blood sugar levels compared to participants who got the placebo.

What medical problems did participants have during the study?

A lot of research is needed to know whether a drug causes a medical problem. So, when new drugs are studied, researchers keep track of all medical problems that participants have during the study. These medical problems are called “adverse events”. They may or may not be caused by the study drug.

How many participants had medical problems in the study?

The table below shows how many participants in each treatment group developed medical problems. The AZD9567 group in the table below includes all participants who took AZD9567, no matter which dose they got. No participants stopped taking the study drug because of a medical problem.

	All AZD9567 (Out of 48 participants)	Steroid (Out of 6 participants)	All placebo (Out of 18 participants)
How many participants developed medical problems?	4 (8.3%)	0	3 (16.7%)

How many participants developed serious medical problems?

A medical problem is considered serious when it is life threatening, causes lasting problems, or needs hospital care. No participants developed serious medical problems in this study, and no participants died during this study.

What were the most common non-serious medical problems in the study?

The table below shows the most common non-serious medical problems that occurred in at least 1 participant in each treatment group. The AZD9567 group includes all participants who took AZD9567, no matter what dose they got.

Non-serious medical problem	All AZD9567 (Out of 48 participants)	Steroid (Out of 6 participants)	All placebo (Out of 18 participants)
Chest pain	1 (2.1%)	0	0
Feeling hot	1 (2.1%)	0	0
Pain at the point that a needle went into a vein	0	0	1 (5.6%)
Common cold	1 (2.1%)	0	0
Cold sores	0	0	1 (5.6%)
Dizziness	1 (2.1%)	0	0
Hot flush	1 (2.1%)	0	0
Nausea	0	0	1 (5.6%)
Sweating too much	0	0	1 (5.6%)

Where can I learn more about the study?

If you have questions about the results, please speak with the doctor or staff at your study site. You can find more information about your study online at www.clinicaltrials.gov/show/NCT02512575.

Official study title: A Single Ascending Dose Study To Assess The Safety, Tolerability, Pharmacokinetics And Pharmacodynamics Of AZD9567

The phone number for the AstraZeneca Information Center is 1-877-240-9479.

The results presented here are for a single study. Other studies may provide new information or different results. You should not make changes to your therapy based on the results of a single study without first consulting your healthcare professional.

Thank you

It is said that the greatest gift is one which is given anonymously, giving when you do not know whether you will get direct personal benefit.

This is the gift that you have given by taking part in a clinical trial. It is a brave and selfless act, one that advances medical knowledge and benefits public health.

Thank you for the gift of your participation in clinical research.



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 trials, nor is it involved in conducting clinical trials.

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