AstraZeneca

Clinical Study Results

Study Sponsor: AstraZeneca AB

Drug Studied: AZD6615

Study Purpose: This study was done to learn more about the safety of AZD6615 in healthy participants

Protocol Number: D7991C00001

Thank you!

Thank you for taking part in the clinical study for the study drug AZD6615.

AstraZeneca AB sponsored this study and believes it is important to share the results. An independent non-profit organization called CISCRP helped prepare this summary of the study results for you.

If you participated in the study and have questions about the results, please speak with the study doctor or staff at your study site.

Who took part in this study?

The researchers asked for the help of healthy men and women. The participants in this study were 21 to 59 years old when they joined.

The study included 24 participants in the United States.

Why was the research needed?

Researchers are looking for a better way to treat people with dyslipidemia. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

Dyslipidemia happens when people have high or abnormal levels of cholesterol and other fats in their blood. This can lead to serious health problems such as heart and blood vessel disease.

Researchers think that the study drug, AZD6615, could help people with dyslipidemia.

What was the purpose of this study?

In this study, the researchers wanted to learn about the safety of AZD6615 in healthy participants.

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

- What signs and symptoms did the participants have during the study?
- 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 AZD6615 helps improve the health of people with dyslipidemia.

What treatments did the participants take?

In this study, all of the participants either took 1 of 3 different doses of AZD6615, or they took 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.

All of the participants took a single dose of study treatment as a tablet by mouth.

This was a "single-blind" study. This means the researchers, study doctors, and other study staff knew what the participants were taking, but the participants did not.

A computer program was used to randomly choose the treatment and dose 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.

The chart below shows the treatments the researchers planned to study.

	AZD6615	Placebo
	18 participants	6 participants
	A single dose of study treatment as a tablet by mouth	

What happened during this study?

The study started in July 2019 and ended in February 2020.

The researchers planned for this study to have 4 parts. But, the researchers stopped the study early after the first part finished. This was because of safety concerns about AZD6615 from other studies that were done in animals.

Before the participants took study treatment, they visited their study site 1 time. This part of the study lasted up to 4 weeks. At this visit, the study doctors made sure the participants could join the study. They also:

- did physical exams and asked about the participants' medications and any medical problems they were having
- took blood and urine samples
- measured the participants' blood pressure, pulse rate, and temperature
- checked the participants' heart health using an electrocardiogram, also known as an "ECG"

The study doctors also did these tests and measurements throughout the study.

While the participants took study treatment, they stayed at their study site for 5 days. They took their dose of study treatment on the second day. They also wore an electronic device to monitor their heart health.

After the participants took study treatment, they visited their study site 6 times. This part of the study lasted for up to 12 weeks. At these visits, the study doctors checked the health of the participants.

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.

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 more information about the study results.

What signs and symptoms did the participants have during the study?

To answer this question, the study doctors did tests and measurements before and after the participants took study treatment.

The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also did ECGs to check the participants' heart health. Overall, the researchers found that there were some small changes in the results of these tests and measurements. But, the researchers did not consider these changes to be meaningful.

The study doctors also kept track of the "adverse events" that the participants had.

An adverse event is any sign or symptom that participants have during a study. Doctors keep track of all the adverse events that happen in studies, even if they do not think the adverse events might be related to the study treatment.

Later in this document, there will be a summary of the adverse events that the study doctors thought might be related to the study treatment. This section is a summary of all the adverse events, whether they might be related to the study treatment or not. An adverse event is considered "serious" when it is life-threatening, causes lasting problems, or the participant needs hospital care.

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

	AZD6615 (out of 18 participants)	**Placebo (out of 6 participants)**
How many participants had adverse events?	27.8% (5)	None
How many participants had serious adverse events?	None	None
How many participants stopped taking study treatment due to adverse events?	None	None

The adverse events in this study were:

- Extreme dizziness, also known as "vertigo"
- Diarrhea
- Infection in the upper airways
- Joint pain
- Headache
- Feeling faint
- Mouth and throat pain

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 drug. These medical problems are called "adverse reactions".

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 AZD6615.

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?

None of the participants in either treatment group had adverse reactions.

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

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of AZD6615 in healthy 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.

Further clinical studies with AZD6615 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 **"NCT04055168"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D7991C00001"** into the search box, and click **"Find a Study"**.

Full Study Title: Phase I Randomized Study to Assess the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of AZD6615 After Single and Multiple Dosing to Healthy Subjects

AstraZeneca AB Protocol Number: D7991C00001

National Clinical Trials Number: NCT04055168

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

Version 1.0_2021_12_01