AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: AZD8601

Study Purpose: This study was done to learn more about the safety of AZD8601 in participants having coronary artery bypass graft surgery for coronary artery disease.

Protocol Number: D9150C00003

Thank you!

Thank you for taking part in the clinical study for the study drug AZD8601.

You and all of the participants helped researchers learn more about AZD8601 to help people who were already having coronary artery bypass graft surgery to treat their coronary artery disease.

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 coronary artery disease in people having coronary artery bypass graft surgery, also called "CABG" surgery. Before a drug can be approved for people to get, 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 got AZD8601 or a placebo as several injections into the heart during CABG surgery. 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:

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

  Overall, the researchers found that from the start of the study, there were some small changes in the results of the participants' health tests and measurements. But, the researchers did not consider these changes to be meaningful.

- **What medical problems did the participants have during this study?**

  None of the participants had any serious adverse reactions, or adverse reactions that resulted in death.

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 those websites.

Who took part in this study?

The researchers asked for the help of men and women who needed a coronary artery bypass graft. The participants in this study were 53 to 79 years old when they joined. The participants had coronary artery disease and the left side of their hearts could not pump as much blood as normal.

All of the participants were having CABG surgery as part of their normal treatment for their coronary artery disease. Their CABG surgeries were planned in advance rather than done as emergency procedures.

The study included 11 participants in Finland and Germany.

Why was the research needed?

Researchers are looking for a better way to treat coronary artery disease in people who are having CABG surgery. Before a drug can be approved for people to get, 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 AZD8601 works in a small number of participants with coronary artery disease who are having CABG surgery. They also wanted to find out if the participants had any medical problems during the study.

In people with coronary artery disease, the blood vessels that carry blood to the heart become narrowed or blocked. This stops the heart from working properly. People with coronary artery disease may have chest pain and are at increased risk of having a heart attack.

CABG surgery helps to restore blood supply to the heart. Surgeons attach a new blood vessel to the coronary artery, which helps the blood avoid the blockage. This new blood vessel is usually taken from the patient's leg or arm.

AZD8601 was designed to increase the amount of a protein called "VEGF-A". VEGF-A helps new blood vessels to grow. AZD8601 was designed to be injected into the heart during CABG surgery to help increase the blood supply to the heart.

In this study, the researchers wanted to find out more about the safety of AZD8601 in participants who were having CABG surgery.

What was the purpose of this study?

The main questions 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 AZD8601 helps improve the health of people who are having CABG surgery.

What treatments did the participants get?

In this study, all of the participants got either AZD8601 or 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 get the drug are actually caused by the drug.

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

A computer program was used to randomly choose the treatment each participant got. 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 participants got either 3 milligrams of AZD8601 or the placebo as injections into the heart during their CABG surgery. The participants were unconscious when they had their surgery and received the injections. There were 7 participants who got AZD8601 and 4 participants who got the placebo.

What happened during this study?

The participants were in the study for up to 9 months. But, the entire study took 3 years and 5 months to finish.

The study started in February 2018 and ended in June 2021.

The chart below shows what happened during the study.

Before the participants had their surgery

2 visits

The study doctors:

- checked the health of the participants to make sure they could join the study
- did a physical exam and asked about the participants' medications and any medical problems
- took blood and urine samples
- checked the participants' heart health and blood flow using 4 different types of scans:
  - positron emission tomography, also called a "PET scan"
  - computed tomography angiography, also called "CT angiography"
  - echocardiography
  - gyrocardiography

The participants:

- answered questionnaires about their symptoms

Up to about 3 months

While the participants were in the hospital

1 visit

The study doctors:

- did a physical exam and asked about the participants' medications and any medical problems
- took blood and urine samples
- checked the participants' heart health using a scan called gyrocardiography

The participants:

- got coronary artery bypass graft surgery
- got 1 dose of AZD8601 or the placebo as several injections into their heart during their surgery

5 days

After the participants left the hospital

1 phone call and 3 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 and blood flow using 4 different types of scans:
  - PET scan
  - CT angiography
  - echocardiography
  - gyrocardiography

The participants:

- answered questionnaires about their symptoms

Up to 6 months

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.

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 got AZD8601. The doctors did physical exams and tested the participants' blood and urine samples to check their overall health. They also checked the participants' heart health using special tests and scans. Some of these scans also measured how well the participants' hearts were pumping out blood.

Overall, the researchers found that from the start of the study 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. 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.

The adverse events that the participants had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. None of the participants had any adverse events that resulted in death.

What medical problems happened during this study?

The medical problems participants have during clinical studies that the study doctors think might be related to the study drug are called "adverse reactions". An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study 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.

The medical problems that the participants had during this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. None of the participants had any serious adverse reactions, or adverse reactions that resulted in death.

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of AZD8601 in participants with coronary artery disease who have coronary artery bypass graft surgery.

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 AZD8601 are 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 **"NCT03370887"** into the search box and click **"Search"**.
- www.clinicaltrialsregister.eu Once you are on the website, click **"Home and Search"**, then type **"2017-002690-19"** in the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com Once you are on the website, type **"D9150C00003"** into the search box and click **"Find a Study"**.

Full Study Title: A randomized, double-blind, placebo-controlled, multi-center, sequential design, phase IIa study to evaluate safety and tolerability of epicardial injections of AZD8601 during coronary artery bypass grafting surgery

AstraZeneca AB Protocol Number: D9150C00003

National Clinical Trials Number: NCT03370887

EudraCT Number: 2017-002690-19

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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