

Clinical Study Results



Research Sponsor: AstraZeneca AB

Drug Studied: AZD8601

Study title: A study to learn if AZD8601 is safe to take for patients with type 2 diabetes

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug AZD8601. This drug is being developed to treat patients with type 2 diabetes. The study started in December 2016 and ended in January 2018.

AstraZeneca AB sponsored this study and thinks 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. 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 doctor or staff at your study site.

Why was the research needed?

Researchers are looking for a better way to treat wounds in patients with type 2 diabetes. Before a drug can be approved for patients 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 if the participants had any medical problems during the study. This information is important to know before other studies can be done that help find out if AZD8601 improves the health of patients with type 2 diabetes.

What kind of study was this?

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

There were 2 parts in this study, Part A and Part B. Participants could only be in 1 part of this study. Participants in part A got either AZD8601 and placebo injections or placebo injections only. Participants in part B got both AZD8601 and placebo injections.

A placebo looks like a drug but does not have any medicine in it. Researchers use a placebo to help make sure that any of the effects they see in the participants who got the drug are actually caused by the drug.

A computer program was used to randomly choose the treatment each participant got. Researchers do this so that comparing the results of each treatment is as accurate as possible.

What happened during the study?

Before the study started, the doctors did a physical examination and asked participants about their medical history and what medicines they were taking to make sure the participants could join the study. They also took blood and urine samples and checked the heart health of participants using an electrocardiogram, also known as an ECG.

During Part A, the participants visited their study site and stayed at the site for up to 9 days. During this visit, the participants got 6 injections that had either AZD8601 and a placebo, or a placebo only.

After the first visit, the participants in Part A visited their study site 8 more times for follow-up visits. At each follow-up visit, the doctors checked the health of the participants again. These visits happened about once a month for 6 months.

During Part B, the participants visited their study site and stayed at the site for up to 3 days. During this visit, the participants got 2 injections that had AZD8601 and 2 injections that had a placebo.

After the first visit, the participants in Part B visited their study site 7 more times for follow-up visits. At each follow-up visit, the doctors checked the health of the participants again. These visits happened about once a month for 6 months.

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. A full list of the questions researchers wanted to answer can be found on the websites listed at the end of this summary. If a full report of the study results is available, it also can 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. In this study, the researchers wanted to learn if AZD8601 is safe to take for patients with type 2 diabetes. So, they studied the medical problems that participants had during the study.

What medical problems did participants have during the study?

The medical problems participants have during clinical studies that the 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.

There were no serious adverse reactions in this study. Some participants had a reaction to the injection, but researchers did not think this was serious. The researchers did not think any other medical problems in this study were related to the study drug. The websites listed at the end of this summary may have other information about medical problems that happened in this study.

How has this study helped patients and researchers?

Researchers thought that a single injection of AZD8601 was safe for participants in this study, but more research is needed to learn if the drug is safe in a larger number of people.

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.

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 a full report of the study results is available, it also can be found here.

- www.clinicaltrials.gov. Once you are on the website, type “**NCT02935712**” into the search box and click “**Search**”.
- www.clinicaltrialsregister.eu. Once you are on the website, click “**Home & Search**”, then type “**2016-002316-40**” in the search box and click “**Search**”.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type “**D9150C00001**” into the search box and click “**Find a Study**”.

The full title of your study is: A Phase I, Randomized, Single-Blind, Placebo Controlled Study to Assess the Safety, Tolerability and Pharmacodynamics of AZD8601 after Single Dose Administration to Male Patients With Type II Diabetes Mellitus (T2DM)

The protocol number of your study is: D9150C00001

AstraZeneca AB sponsored this study and has its headquarters at 151 85 Södertälje, Sweden.

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

Thank you!

Clinical trial 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 participants.



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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