AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca

Treatment Studied: Dapagliflozin

Study Purpose: This study was done to learn if dapagliflozin is safe and works in participants with type 2 diabetes

Protocol Number: D1690C00060

Thank you

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

You and all of the participants helped researchers learn more about dapagliflozin to help people with type 2 diabetes, also called "T2D".

AstraZeneca 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.

Who took part in this study?

The researchers asked for the help of men and women with T2D.

The participants in this study were 18 to 65 years old when they joined. The study included 304 participants in China.

Why was the research needed?

Researchers are looking for a better way to treat T2D. 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 people with T2D, the body does not use insulin as well as it should. Insulin is a hormone that controls the levels of blood sugar, also called "glucose". T2D can cause blood glucose levels to rise too high. This can cause medical problems.

Researchers can measure blood glucose levels by looking at a protein in red blood cells called "hemoglobin". When red blood cells are carrying glucose, the hemoglobin changes shape and is called "HbA1c". Lower levels of HbA1c mean better control of blood glucose levels.

Dapagliflozin is a drug that may help lower levels of HbA1c by helping the kidneys remove glucose through the urine. Acarbose is a drug that can help lower HbA1c and is already approved to treat people with T2D. In this study, acarbose was used as an "active comparator". An active comparator is a drug that is already approved to treat people. In clinical studies, researchers will sometimes compare how well the study drug works to how well the active comparator works.

Researchers already did studies that showed that dapagliflozin worked for the people with T2D who were in those studies. In this study, the researchers wanted to find out more about how it works.

What was the purpose of this study?

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

- Did dapagliflozin work at least as well as acarbose to lower the levels of HbA1c?
- 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 dapagliflozin helps improve the health of people with T2D.

What treatments did the participants take?

In this study, the participants took either dapagliflozin or acarbose as capsules by mouth. The doses were measured in milligrams, also known as "mg".

It was planned for the participants to take 1 of the following treatments:

- 10 mg of **dapagliflozin**, once a day
- 50 mg or 100 mg of **acarbose**, 1 to 3 times a day

This was an "open-label" study. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

A computer program was used to randomly choose the treatment 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.

	Group 1	Group 2
Participants	150	154
Treatment	Dapagliflozin as capsules by mouth	Acarbose as capsules by mouth
Dose	10 mg, once a day	• Week 1: 50 mg, once a day • Week 2: 50 mg, twice a day • Week 3: 50 mg, 3 times a day • Week 4 and after: 100 mg, 3 times a day

What happened during this study?

The researchers planned for the participants to take study treatment for 24 weeks, which is about 6 months. This study was ended early by the sponsor. Some participants completed all 24 weeks of study treatment before the study was ended. Other participants were in the study for less time because the study was ended before they could complete the study treatment, or because they left for another reason.

The entire study lasted for about 1 and a half years. The study started in December 2017 and ended in May 2019.

The chart below shows what happened during the study.

Before the participants took study treatment

3 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 urine samples
- took blood samples before and after the participants ate a meal
- checked the participants' heart health using an electrocardiogram, also called an ECG

The participants:

- answered questions about their health

Up to 2 weeks

While the participants took study treatment

5 visits

At some visits, the study doctors:

- did a physical exam and asked about the participants' medications and any medical problems
- took urine samples
- took blood samples before and after the participants ate a meal
- checked the participants' heart health using an electrocardiogram, also called an ECG

The participants:

- took the study treatment
- answered questions about their health
- wrote down information related to blood sugar in a glycemia diary
- measured their blood sugar levels using a glucometer

24 weeks

After the participants took study treatment

1 phone call

The study doctors:

- called the participants to ask about about their health

The participants:

- answered questions about their health

Up to 1 week

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.

Did dapagliflozin work at least as well as acarbose to lower the levels of HbA1c?

To answer this question, the researchers planned to compare the participants' HbA1c levels before taking dapagliflozin or acarbose, and after 24 weeks of taking dapagliflozin or acarbose. But, the study was ended early by the sponsor. Because of this, the researchers could not answer this question. The reason the study was ended early was not related to safety problems.

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". 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 drug. A lot of research is needed to know whether a drug causes an adverse reaction.

The adverse reactions that the participants had during this study are not in this summary. The researchers could not accurately report adverse reactions because the study ended early.

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.

How has this study helped patients and researchers?

This study helped researchers learn more about whether dapagliflozin worked at least as well as acarbose in participants with T2D.

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.

Further clinical studies with dapagliflozin 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 **"NCT03344341"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D1690C00060"** into the search box and click **"Find a Study"**.

Full Study Title: A 24-Week, Multicenter, Randomized, Parallel-group, Open-label, Active Controlled Phase IV Study to Assess the Efficacy and Safety of Dapagliflozin as Monotherapy Compared With Acarbose in Drug-Naïve Patients with Type 2 Diabetes Mellitus (T2DM) in China

AstraZeneca Protocol Number: D1690C00060

National Clinical Trials Number: NCT03344341

AstraZeneca sponsored this study and has its headquarters in Cambridge, United Kingdom.

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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