Clinical Study Results

Research Sponsor: AstraZeneca

Drugs Studied: Dapagliflozin

Study Title: A study to learn about how dapagliflozin affects the heart in participants with type 2 diabetes

Thank you!

Thank you to the participants who took part in the clinical study investigating the effects of the study drug dapagliflozin. All of the participants helped researchers learn more about dapagliflozin and learn more about type 2 diabetes.

AstraZeneca sponsored this study and thinks it is important to share the results of the study with the participants and the public. An independent non-profit organization called CISCRP helped prepare this summary of the study results. We hope it helps the participants understand and feel proud of their 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.

What is happening with the study now?

The study started in February 2018 and ended in March 2019. The entire study took 13 months to finish until enough participants had completed it. Each participant was in the study for up to 11 weeks.

The study included 53 participants in Sweden and Finland.

The sponsor reviewed the data collected when the study ended and created a report of the results. This is a summary of that report.

Why was the research needed?

Researchers are looking for a better way to treat people who have type 2 diabetes, also called T2DM.

Dapagliflozin is a drug that is already used to treat people with T2DM. In this study, the researchers wanted to find out more about how dapagliflozin affects the heart in participants with T2DM.

T2DM is a condition that causes the levels of blood sugar to rise higher than normal. T2DM can also cause damage to the heart. This damage can cause heart failure, cardiovascular events and increase the risk of death.

Treatments for T2DM, such as dapagliflozin, can help lower blood sugar. In earlier studies in patients with T2DM, researchers found that dapagliflozin reduced the risk of cardiovascular events for those patients. Researchers wanted to find out if dapagliflozin improved how well the heart works in people with T2DM.

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

- How did dapagliflozin affect the function of the heart?
- What medical problems did the participants have during the study?

To answer the questions in this study, researchers asked for the help of men and women with T2DM. The participants in this study were between 45 and 74 years old. They did not have any heart problems or other serious medical problems.

What kind of study was this?

This was a “double-blind” study. This means none of the participants, doctors, or other study staff knew what treatment each participant received. 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 each participant took so they could review the information collected and report the study results.

The participants in this study took either dapagliflozin 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 take the drug are actually caused by the drug.

Dapagliflozin and a placebo were taken as tablets. The dose of dapagliflozin was measured in milligrams, also known as mg. The participants took 10 mg of dapagliflozin or a placebo tablet once a day in the morning.

A computer program was used to randomly choose the group each participant was in. This helps make sure the groups are chosen fairly. Researchers do this so that comparing the results of each group is as accurate as possible.

In this study, 27 participants were in the dapagliflozin group and 26 participants were in the placebo group.

Not every participant took study treatment or completed the study.

- There was 1 participant who did not take dapagliflozin and 1 participant who left the study early and did not finish getting the study treatment.
- There were 2 participants who took placebo whose information was not included in the study results because the study instructions were not followed properly.

So, their information is not included here and the results below include information for the 49 participants who completed the study.

What happened during the study?

Before the participants took study treatment, the participants visited their study site 1 time. At this visit, the doctors checked the overall health of the participants to make sure they could join the study.

The doctors:

- did a physical exam
- took blood samples
- checked the participants' heart health using an echocardiogram, if not done recently at the hospital, and an electrocardiogram
- asked about the participants' health and medications

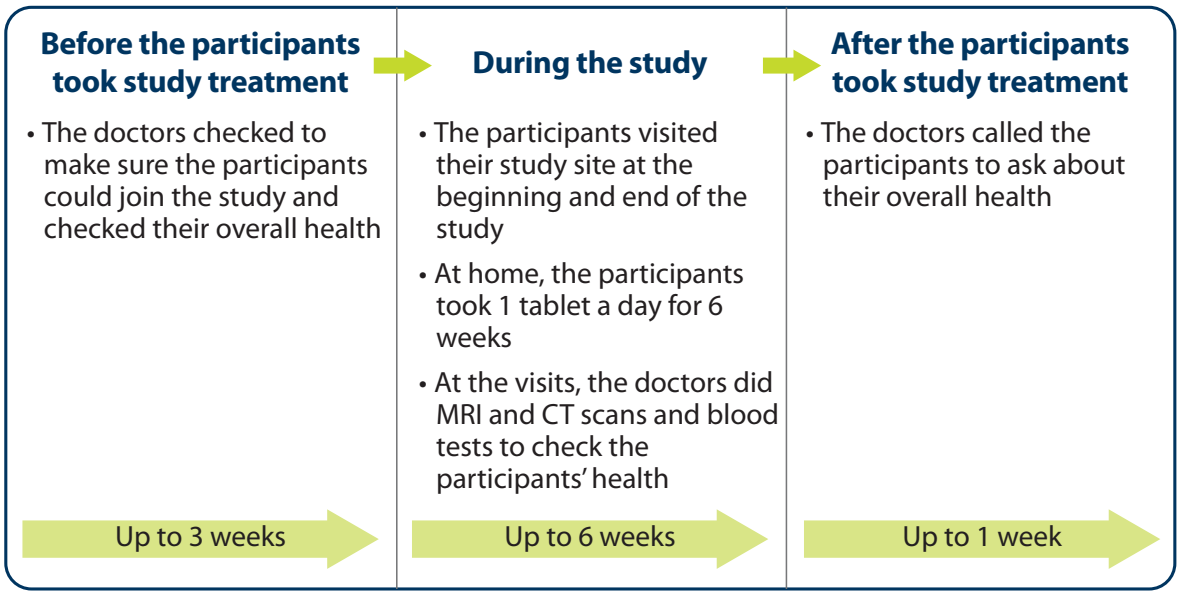
During the study, the participants visited their study site 2 times. At the first visit, the participants got the dapagliflozin or placebo tablets to take home. The participants took 1 tablet each day at home for 6 weeks. The second visit was at the end of the 6 weeks.

At each visit, the doctors:

- did a physical exam
- did an MRI scan, also known as a magnetic resonance imaging scan, and a CT scan, also known as computerized tomography scan, to check the heart
- took blood and urine samples

The participants also received a phone call from the doctors in week 2 of the study, between the visits. This was done to check on the participants' overall health.

After the participants took the last study treatment, they received a phone call 1 week afterwards from the doctors to ask about their overall health.



What were the results of the study?

This is a summary of the main results from this study overall. The results of each participant 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. 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.

How did dapagliflozin affect the function of the heart?

Overall, there were some changes in heart function in the participants who had taken dapagliflozin. But, the differences between these participants and the participants who had taken the placebo was too small for the researchers to know how dapagliflozin affected the function of the heart.

The researchers took pictures of each participant's heart using MRI and CT. To learn how the heart was working, they used a measurement called the global longitudinal strain of the left ventricle, also called GLSLV or heart strain.

Heart strain, is a measurement of the shape and length of the heart muscle and how well it contracts. It is measured as a percentage. A change in heart strain percentage can mean there is a change in heart function.

The researchers compared the participants' heart strain percentage before they got any treatment to their heart strain percentage at the end of the study. They then calculated the average change in heart strain percentage. They compared the change in the participants who took dapagliflozin and the change in those who took the placebo.

The researchers found that there was a small change in the heart strain percentage in both groups. But, the differences between the groups were too small for the researchers to conclude that dapagliflozin affected the function of the heart.

What medical problems did the participants have during the 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 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 many participants had serious adverse reactions?

None of the participants had serious adverse reactions during the study.

None of the participants died due to serious adverse reactions during the study.

How many participants had adverse reactions?

None of the participants had adverse reactions during the study.

None of the participants stopped treatment because of adverse reactions.

How has this study helped patients and researchers?

This study helped researchers learn more about how dapagliflozin affects the heart in participants with T2DM.

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 results from this study, as well as future studies may provide new information or different results.

Further clinical studies with this study drug 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 can also be found here.

- www.clinicaltrials.gov. Once you are on the website, type "**NCT03387683**" into the search box, and click "**Search**".
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2017-003820-58"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D1690C00063"** into the search box, and click **"Find a Study"**.

Full Trial Title: A double-blind, randomized, parallel group, Phase IV study to investigate the effects of DAPAgliflozin on CARDiac substrate uptake, myocardial efficiency and myocardial contractile work in type 2 diabetes patients

National Clinical Trials number: NCT03387683

EudraCT Number: 2017-003820-58

AstraZeneca Protocol Number: D1690C00063

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

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