# Clinical Study Results

**Research Sponsor:** AstraZeneca AB

**Drugs Studied:** Dapagliflozin

**Study Title:** A study to find out how dapagliflozin affects blood sugar levels in young people with type 2 diabetes

## *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 young people with type 2 diabetes, also called T2DM.

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

Researchers are looking for a better way to treat T2DM in young people. Before a drug can be approved for participants to take, 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 took dapagliflozin and a placebo. A placebo looks like a drug but does not have any medicine in it.

### What were the results of the study?

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

- **Did dapagliflozin affect HbA1c levels in the participants' blood after 24 weeks of treatment?**
  No. Researchers measure HbA1c levels as a way of measuring blood sugar levels. Overall, the researchers found there were some changes in the average HbA1c levels in the participants who took dapagliflozin and the participants who took the placebo. But, these changes were not enough for the researchers to know if dapagliflozin affected HbA1c levels.
- **What medical problems did the participants have during the study?**
  There were 16.7% of participants who had medical problems that the study doctors thought might be related to the study drug during the study. More details about the medical problems that the participants had during the study are included later in this summary.

### Where can I learn more about this study?

You can find out more information about this study on the websites listed on the last page. When a full report of the study results is available, it can also be found on those websites.

## Who took part in the study?

The researchers asked for the help of young people with T2DM. The participants in this study were 11 to 24 years old when they joined.

The study included 72 participants in Hungary, Israel, Mexico, Russia, the United Kingdom, and the United States.

## Why was the research needed?

Researchers are looking for a better way to treat T2DM in young people. 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 T2DM, the body does not make enough insulin. Insulin is a hormone that controls the level of blood sugar, which is also called glucose. T2DM causes blood glucose levels to rise higher than normal. 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 improved control of blood glucose levels.

In this study, the researchers wanted to find out if dapagliflozin affected the HbA1c levels in a large number of participants with T2DM. They also wanted to find out if the participants had any medical problems during the study.

## What was the purpose of this study?

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

- Did dapagliflozin affect HbA1c levels in the participants' blood after 24 weeks of treatment?
- 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 dapagliflozin helps improve the health of young people with T2DM.

## What treatments did the participants take?

In this study, all of the participants took dapagliflozin and a placebo as tablets by mouth. 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. The dose of dapagliflozin was 10 milligrams, also known as mg. All of the participants continued taking their regular T2DM treatments throughout the study.

There were 3 main parts in this study.

**Part 1** of the study was “single-blind”. This means the researchers, study doctors, and other study staff knew what the participants were taking but the participants did not. In Part 1, all of the participants took the placebo once a day for 4 weeks.

**Part 2** of the study was “double-blind”. This means none of the participants, researchers, study doctors, or other study staff knew what treatment each participant was taking. Some studies are done this way because knowing what treatment the participants are taking can affect the results of the study. When the study ended, the research sponsor found out which treatment the participants took so they could create a report of the study results.

In Part 2, the participants took either dapagliflozin or the placebo once a day for 24 weeks. 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.

**Part 3** of the study was “open-label”. This means the participants, researchers, study doctors, and other study staff knew what each participant was taking. In Part 3, all of the participants took dapagliflozin once a day for 28 weeks.

The chart below shows the treatments that were planned.

| Part 1 | Part 2 | | Part 3 |
|---|---|---|---|
| 72 participants would take the placebo | 39 participants would take 10 mg of dapagliflozin | 33 participants would take the placebo | 72 participants would take 10 mg of dapagliflozin |
| As a tablet by mouth | As a tablet by mouth | As a tablet by mouth | As a tablet by mouth |
| Once a day for 4 weeks | Once a day for 24 weeks | Once a day for 24 weeks | Once a day for 28 weeks |

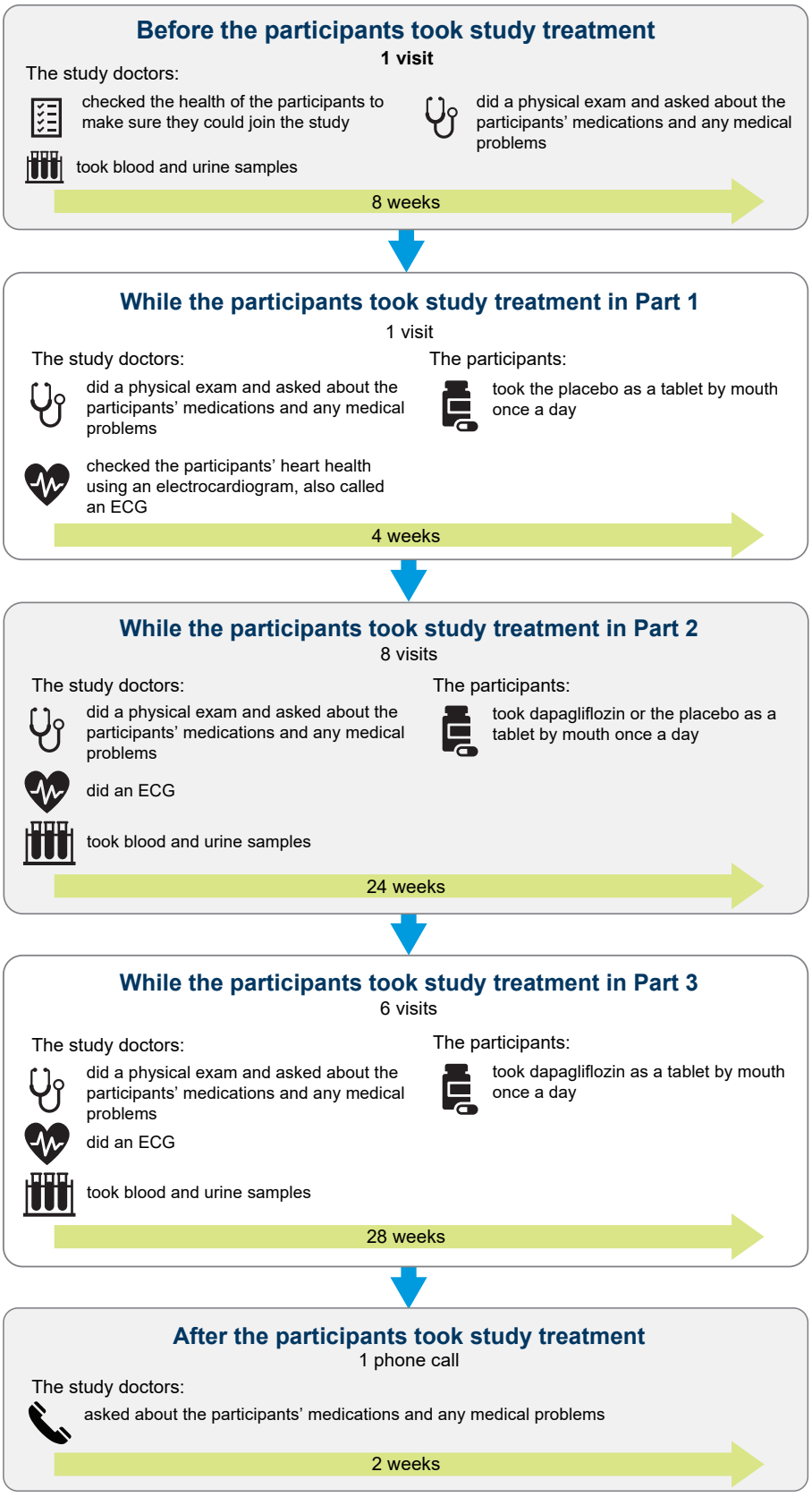
## What happened during the study?

The participants were in the study for just over 1 year. But the entire study took almost 4 years to finish.

The study started in June 2016 and ended in April 2020.

Throughout the study, the study team gave the participants advice about their diet and exercise. They also gave the participants a finger-prick glucose meter to use at home between visits.

The chart below shows what happened during the study.



# 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. 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 affect HbA1c levels in the participants' blood after 24 weeks of treatment?

No. Overall there were some changes in the average HbA1c levels in the participants who took dapagliflozin and the participants who took the placebo. But, these changes were not enough for the researchers to know if dapagliflozin affected HbA1c levels.

To answer this question, the researchers measured the amount of HbA1c in the participants' blood before and after they took treatment in Part 2 of the study. They calculated the average percent change in the participants' HbA1c levels after 24 weeks for those who took dapagliflozin and for those who took the placebo. This was at the end of Part 2.

The researchers found that the average change in HbA1c levels in the participants' blood after 24 weeks was:

- a **decrease** of 0.25% for the participants taking dapagliflozin
- an **increase** of 0.50% for the participants taking the placebo

# What medical problems happened 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. These adverse reactions have been, and will continue to be, reviewed together with all of the available data for the study drug.

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?

| | Dapagliflozin (out of 39 participants) | Placebo (out of 33 participants) |
|---|---|---|
| How many participants had adverse reactions? | 17.9% (7) | 15.2% (5) |
| How many participants had serious adverse reactions? | 0.0% (0) | 0.0% (0) |
| How many participants stopped getting study treatment because of adverse reactions? | 2.6% (1) | 0.0% (0) |

### What serious adverse reactions happened during this study?

None of the participants had serious adverse reactions in this study.

### What adverse reactions happened during this study?

The most common adverse reactions are shown in the table below. These happened in 2 or more participants. There were other adverse reactions but these happened in fewer participants.

| | Dapagliflozin (out of 39 participants) | Placebo (out of 33 participants) |
|---|---|---|
| Nausea | 5.1% (2) | 0.0% (0) |
| Fungal infection | 2.6% (1) | 3.0% (1) |
| Urinary tract infection | 2.6% (1) | 3.0% (1) |
| Frequent passing of large amounts of urine | 2.6% (1) | 3.0% (1) |
| Frequent urination during the day | 2.6% (1) | 3.0% (1) |
| Painful or difficult urination | 2.6% (1) | 3.0% (1) |

## How has this study helped patients and researchers?

This study helped researchers learn more about dapagliflozin in young people 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 studies may provide new information or different results.

Further clinical studies with dapagliflozin are ongoing.

# 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 **"NCT02725593"** into the search box, and click **"Search"**.
- www.clinicaltrialsregister.eu. Once you are on the website, click **"Home and Search"**, then type **"2015-005041-31"** in the search box, and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D1690C00017"** into the search box, and click **"Find a Study"**.

**Full Study Title:** A 24-Week, Multicentre, Randomised, Double-Blind, Parallel Group, Phase 3 Trial with a 28-Week Long-Term Safety Extension Period Evaluating the Safety and Efficacy of Dapagliflozin 10 mg in T2DM Patients Aged 10–24 Years

**AstraZeneca Protocol Number:** D1690C00017

**National Clinical Trials number:** NCT02725593

**EudraCT number:** : 2015-005041-31

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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