AstraZeneca

Clinical Study Results

Research Sponsor: AstraZeneca AB

Drug Studied: Dapagliflozin and saxagliptin

Study Title: This study was done to learn how dapagliflozin worked when taken with saxagliptin and metformin and about its safety in Asian participants with type 2 diabetes

Protocol Number: D1683C00008

Thank you!

Thank you for taking part in the clinical study for the study treatments dapagliflozin, saxagliptin, and metformin.

You and all of the participants helped researchers learn more about dapagliflozin, saxagliptin, and metformin to help Asian 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 of this study

Why was the research needed?

Researchers are looking for a different way to treat type 2 diabetes. Before a drug can be approved for people to take, researchers do clinical studies to find out how safe it is and how it works.

What treatments did the participants take?

The participants in this study took either dapagliflozin with saxagliptin and metformin, or a placebo with saxagliptin and metformin. 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 with saxagliptin and metformin affect the levels of HbA1c in the participants' blood?**

HbA1c is a protein in the blood that researchers measure as a way of assessing blood sugar levels. Because the sponsor decided to stop the study early, the researchers did not have enough information to compare the HbA1c levels of the participants. So, they could not answer this question.

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

There were 4.9% of participants who had medical problems that the study doctors thought might be related to the study treatments during the study. This was 2 out of 41 participants. 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 these websites.

Who took part in the study?

The researchers asked for the help of Asian men and women with T2DM who were already taking metformin but were still not able to control their blood sugar levels. The participants in this study were 31 to 73 years old when they joined.

The study included 49 participants in Vietnam and Thailand. The researchers also planned to include participants from China. But, the study was stopped early before any participants in China joined.

Why was the research needed?

Researchers are looking for a different way to treat people who have T2DM who are not able to control their blood sugar levels, even with treatment. 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 or does not use insulin as well as it should. Insulin 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.

Doctors can measure average levels of blood glucose by looking at a protein in red blood cells called hemoglobin. In people with T2DM, extra glucose in the blood attaches to hemoglobin, creating a protein called HbA1c. Lower levels of HbA1c mean lower blood glucose levels.

In this study, the researchers wanted to find out how dapagliflozin, saxagliptin, and metformin affected HbA1c levels in Asian participants with T2DM when taken together. 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 with saxagliptin and metformin affect the levels of HbA1c in the participants' blood?
- 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 with saxagliptin and metformin helps improve the health of people with T2DM.

What treatments did the participants take?

In this study, the participants took either 1 of 2 different doses of 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. All of the participants also took both saxagliptin and metformin.

There were 2 main parts to this study. The researchers planned for the same participants to be in both parts. In Part 1, all of the participants took saxagliptin and metformin for 8 to 16 weeks, depending on what other treatments they were already taking. Part 1 was "open-label". This means the participants, researchers, study doctors, and other study staff knew what each participant was taking.

In Part 2, there were 3 groups of participants. Each group took 1 of 2 different doses of dapagliflozin or the placebo. All of the participants continued taking saxagliptin and metformin. Part 2 lasted for 24 weeks and was "double-blind". This means none of the participants, researchers, study doctors, or other study staff knew what each participant was taking.

A computer program was used to randomly choose the treatment each participant took in Part 2. 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.

All of the study treatments were taken as tablets by mouth, once a day. The doses of dapagliflozin and saxagliptin were measured in milligrams, also known as mg. All of the participants continued taking the same dose of metformin that they were already taking before the study.

There were 8 participants who did not continue into Part 2, so Part 2 only included 41 participants.

The chart below shows the treatments that the participants took in **Part 2**:

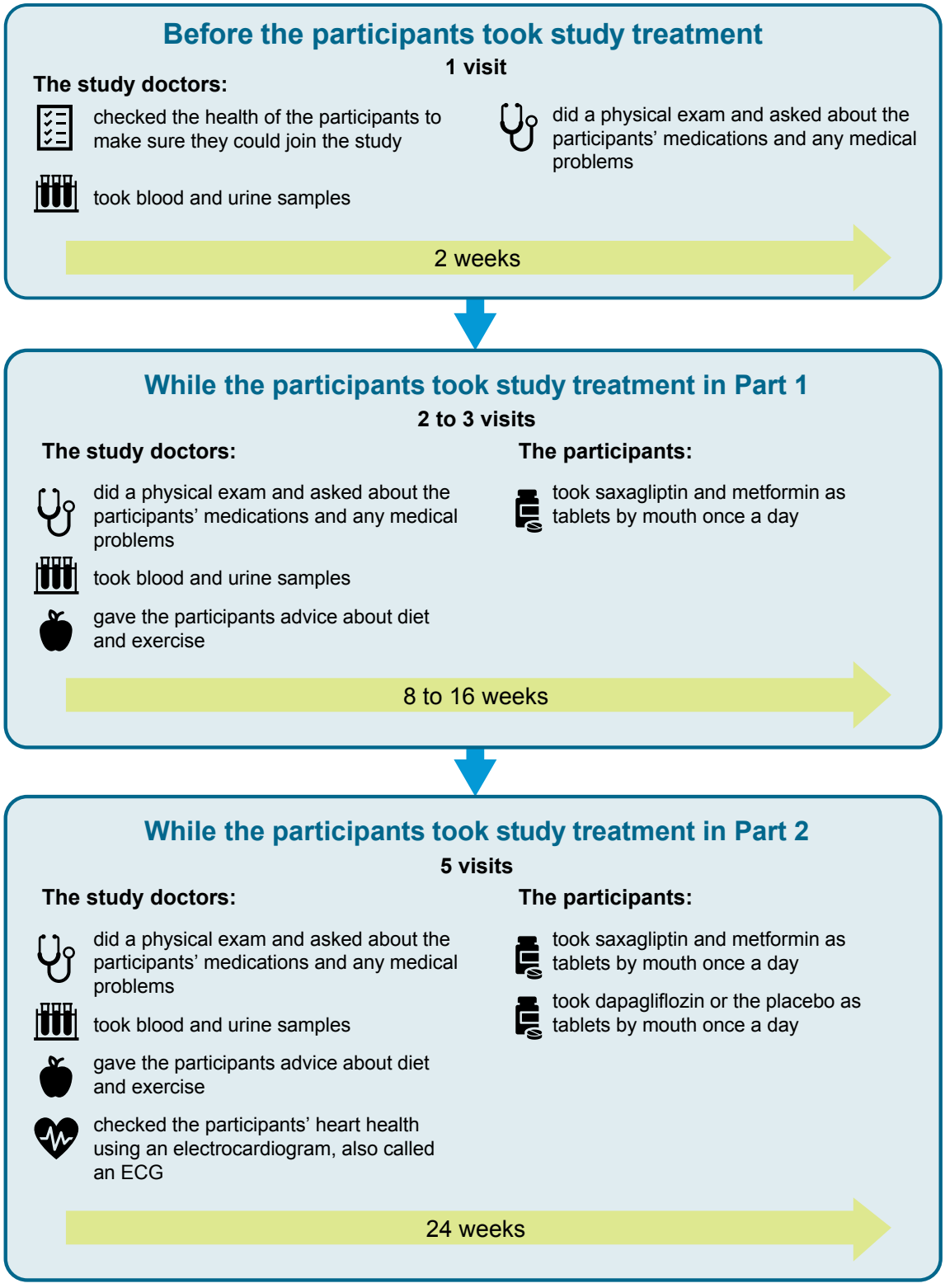
	Group 1 (13 participants)	**Group 2 (13 participants)**	**Placebo (15 participants)**
	• 10 mg of dapagliflozin • 5 mg of saxagliptin • Their regular dose of metformin	• 5 mg of dapagliflozin • 5 mg of saxagliptin • Their regular dose of metformin	• A placebo that looks like dapagliflozin • 5 mg of saxagliptin • Their regular dose of metformin
	• Tablets by mouth, once a day for 24 weeks		

What happened during the study?

The participants were in the study for up to 9.5 months. But, the entire study took 18 months to finish.

The study started in February 2019 and ended in August 2020. The study ended early because the sponsor decided to stop researching the combination of dapagliflozin, saxagliptin, and metformin together. This was not related to the safety of the combination of study treatments.

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 with saxagliptin and metformin affect the levels of HbA1c in the participants' blood?

Because the sponsor decided to stop the study early, the researchers did not have enough information to answer this question.

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 treatments. 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 treatments. A lot of research is needed to know whether a treatment 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 treatments.

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.

There were participants who had adverse reactions in this study.

None of the participants had adverse reactions during **Part 1** of the study. There were 4.9% of participants who had adverse reactions during **Part 2** of the study. This was 2 out of 41 participants.

- 7.7% of participants in Group 1 had an adverse reaction. This was 1 out of 13 participants.
- None of the participants in Group 2 had an adverse reaction.
- 6.7% of participants in Group 3 had an adverse reaction. This was 1 out of 15 participants.

There were no participants who had serious adverse reactions during the study.

There were no participants who stopped taking treatment due to adverse reactions during the study.

The only adverse reaction that happened during this study was a urinary tract infection.

- 7.7% of participants in Group 1 had a urinary tract infection. This was 1 out of 13 participants.
- None of the participants in Group 2 had a urinary tract infection.
- 6.7% of participants in Group 3 had a urinary tract infection. This was 1 out of 15 participants.

How has this study helped patients and researchers?

This study helped researchers learn more about the safety of dapagliflozin, saxagliptin, and metformin in Asian 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 1 study. Other studies may provide new information or different results.

Further clinical studies with dapagliflozin and metformin 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 **"NCT03608358"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D1683C00008"** into the search box, and click **"Find a Study"**.

Full Study Title: A Multicenter, Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Therapy with Dapagliflozin Added to Saxagliptin in Combination with Metformin Compared to Therapy with Placebo added to Saxagliptin in Combination with Metformin in Asian Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin and Saxagliptin (DS Navigation)

AstraZeneca AB Protocol Number: D1683C00008

National Clinical Trials number: NCT03608358

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!

Participants in clinical studies 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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