Clinical Study Results

AstraZeneca

Research Sponsor: AstraZeneca

Drug Studied: Dapagliflozin

Study title: A study to learn more about how dapagliflozin affects body fat levels compared to glimepiride in patients with type 2 diabetes who are taking metformin

Thank you!

Thank you to the participants who took part in the clinical trial for the study drug dapagliflozin. You and all of the other participants helped researchers learn more about dapagliflozin to help people with type 2 diabetes.

AstraZeneca sponsored this study and thinks it is important to share the results with the participants 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 doctor or staff at your study site.

What is happening with the study now?

The participants were in the study for up to about 1 year. The entire study took 2 years to finish, starting in January 2016 and ending in January 2018.

The study included 121 participants in the Republic of Korea.

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 patients with type 2 diabetes. Before a drug can be approved for patients to take, researchers do clinical studies to find out how safe it is and how it works.

Researchers already did studies that showed dapagliflozin worked for study participants with type 2 diabetes. In this study, the researchers wanted to find out more about how dapagliflozin affects body fat levels in participants with type 2 diabetes who were taking metformin.

When a person has type 2 diabetes, the body cannot control the levels of sugar in the blood. This can lead to several medical problems. In many cases, the cause of type 2 diabetes is being overweight or obese. But, few of the current type 2 diabetes treatments help people to lose body fat and control body weight.

An approved type 2 diabetes drug, metformin, is commonly used to control blood sugar and fat levels in the body. But, some type 2 diabetes patients have to take additional drugs to help control these levels. Two of these approved drugs that can be used together with metformin are dapagliflozin and glimepiride.

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

- How did dapagliflozin affect the fat levels in the body compared to glimepiride?
- What medical problems did the participants have during the study?

To answer the questions in this study, the researchers asked for the help of men and women with type 2 diabetes who were already taking metformin. These men and women had also reported that their blood sugar levels had been too high or too low within 4 weeks of the start of this study. Everyone in the study was 26 to 73 years old when they joined.

What kind of study was this?

This was an “open-label” study. This means the researchers and the participants knew what drugs the participants were taking.

The participants in the study took either:

- dapagliflozin and metformin
- glimepiride and metformin

All of the drugs were taken as a pill by mouth.

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.

What happened during the study?

Before the study started, the doctors:

- did a physical examination of the participants
- checked the height, weight, blood sugar levels, and body fat levels of the participants
- took blood and urine samples
- checked the heart health of the participants using an electrocardiogram, also known as an ECG
- did a body scan called a Dual Energy X-Ray Absorptiometry, or DXA scan, to measure the amount of body fat of the participants
- did a scan called a computed tomography, or CT scan, on the abdomen to measure the amount of fat in the abdomen
- asked about the medical history of the participants, how they were feeling, and what medicines they were taking

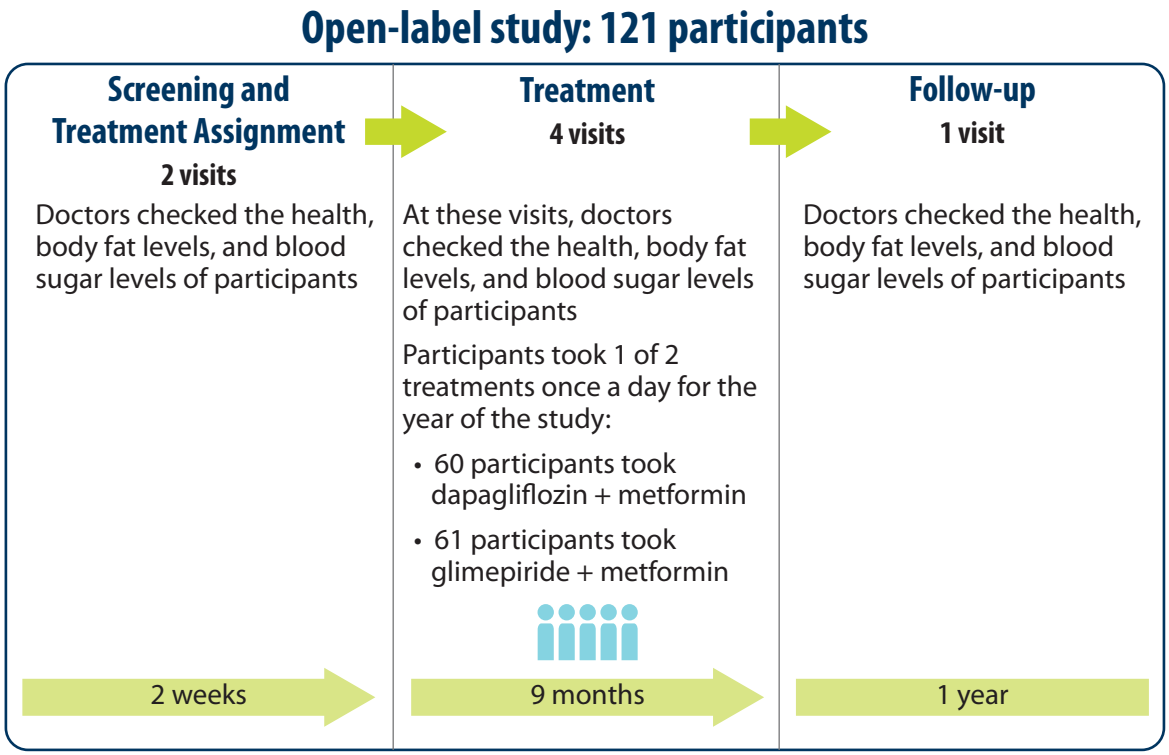
During the study, the participants visited their study site 5 times over the course of 1 year. At these visits, the doctors checked the weight, blood sugar levels, and body fat levels, and overall health of the participants.

Over the course of the study, the participants took either:

- dapagliflozin and metformin once a day
- glimepiride and metformin once a day

At the end of the study, the participants visited their study site again for a follow-up visit. During this visit, the doctors checked the health of the participants again and asked how they were feeling.

The figure below shows how the study was done.



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 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 change.

How did dapagliflozin affect the fat levels in the body compared to glimepiride?

Overall, the researchers found that the participants who took dapagliflozin and metformin had a larger decrease in their body fat levels compared to the participants who took glimepiride and metformin. Participants who took glimepiride and metformin had increased body fat levels.

To answer this question, the researchers measured the following in the participants:

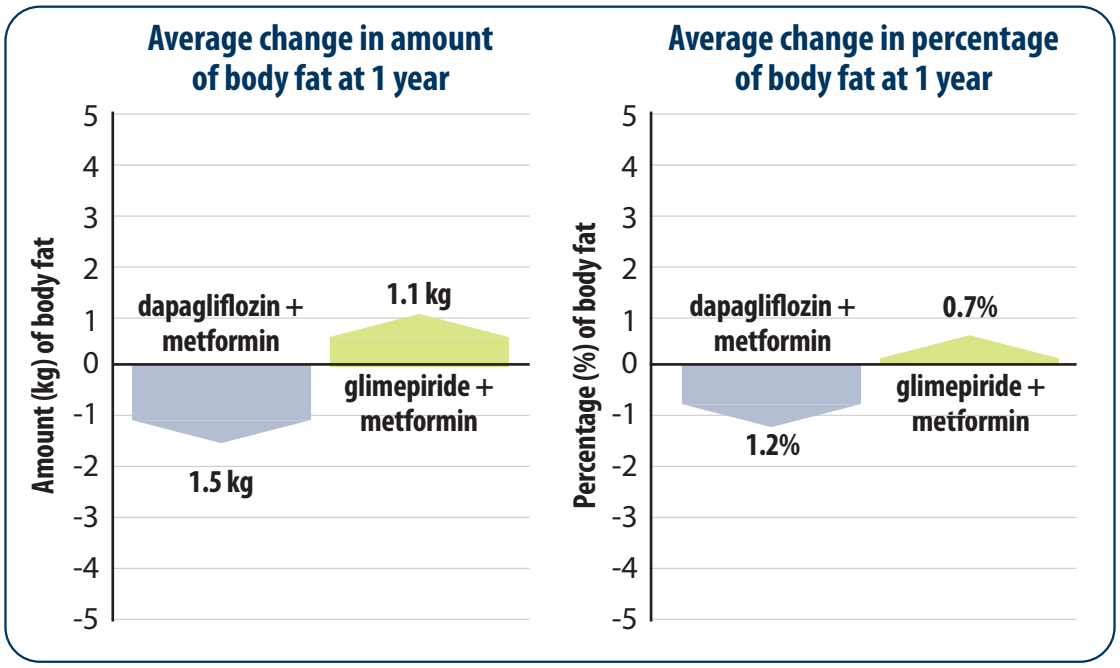
- change in amount of body fat at 1 year
- change in percentage of body fat at 1 year

The researchers measured body fat amounts in kilograms, also known as kg.

At 1 year of treatment, the researchers found that:

- Participants who took dapagliflozin and metformin had an average decrease of 1.5 kg of body fat. This was an average decrease of 1.2%.
- Participants who took glimepiride and metformin had an average increase of 1.1 kg of body fat. This was an average increase of 0.7%.

The figure below shows these results.



What medical problems did 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 drug reactions”. An adverse drug reaction is considered “serious” when it is life-threatening, causes lasting problems, or requires hospital care.

These adverse drug 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 more information about the adverse drug reactions or other medical problems that happened during this study.

How many participants had adverse drug reactions?

There were 14% of participants who had adverse drug reactions during the study. This was 17 out of 121 participants.

The table below shows how many participants had adverse drug reactions.

Adverse drug reactions			
	Dapagliflozin + Metformin (Out of 60 participants)	**Glimepiride + Metformin (Out of 61 participants)**	**Total (Out of 121 participants)**
How many participants had adverse drug reactions?	16.7% (10)	11.5% (7)	14.0% (17)
How many participants had serious adverse drug reactions?	0.0% (0)	0.0% (0)	0.0% (0)
How many participants left the study because of adverse drug reactions?	3.3% (2)	1.6% (1)	2.5% (3)

What adverse drug reactions did the participants have?

The most common adverse drug reaction was hypoglycemia, also called low blood sugar.

The table below shows the adverse drug reactions that happened during the study.

Adverse drug reactions that happened during the study			
Adverse drug reaction	**Dapagliflozin + Metformin (Out of 60 participants)**	**Glimepiride + Metformin (Out of 61 participants)**	**Total (Out of 121 participants)**
Low blood sugar	5.0% (3)	8.2% (5)	6.6% (8)
Weight loss	3.3% (2)	0.0% (0)	1.7% (2)
Frequent need to urinate	1.7% (1)	0.0% (0)	0.8% (1)
Itching in genital area	1.7% (1)	0.0% (0)	0.8% (1)
Swelling in urethra	1.7% (1)	0.0% (0)	0.8% (1)
Trouble urinating	1.7% (1)	0.0% (0)	0.8% (1)
Urinary tract infection	1.7% (1)	0.0% (0)	0.8% (1)
Vaginal itching	1.7% (1)	0.0% (0)	0.8% (1)
Indigestion	0.0% (0)	1.6% (1)	0.8% (1)
Upper stomach pain	0.0% (0)	1.6% (1)	0.8% (1)

None of the participants died during the study.

How has this study helped participants and researchers?

These results helped researchers learn more about how dapagliflozin affects the body fat levels compared to glimepiride in patients with type 2 diabetes who were taking metformin.

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 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 **"NCT02564926"** into the search box and click **"Search"**.
- www.AstraZenecaClinicalTrials.com. Once you are on the website, type **"D1690L00067"** into the search box and click **"Find a Study"**.

Full trial title: Effects of Dapagliflozin Compared with Glimepiride on Body Composition in Patients with Type 2 Diabetes Inadequately Controlled with Metformin

Protocol number: D1690L00067

AstraZeneca sponsored this study and has its headquarters at 1800 Concord Pike in Wilmington, Delaware.

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 participants.