

**Research sponsor:** AstraZeneca K.K.

**Drug studied:** Dapagliflozin

**Short study title:** A study to learn how dapagliflozin combined with insulin acts in the body and if dapagliflozin is safe to take with insulin

---

## ***Thank you!***

Thank you for taking part in the clinical trial for the study drug dapagliflozin. The study started in October 2015 and ended in June 2016.

AstraZeneca K.K. sponsored this study and thinks it is important to share the results of the study with you and the public. An independent, non-profit organization called CISC RP and a medical writing organization called Synchrogenix helped prepare this summary of the study results. 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.

## **Why was the research needed?**

Researchers are looking for a better way to treat type 1 diabetes. Before a drug can be approved for patients to take, researchers do clinical studies to find out how it works and how safe it is.

The researchers wanted to find out if the participants had any medical problems during the study. They also wanted to find out how dapagliflozin works in the body when taken with insulin. This information is important to know before other studies can be done that help find out if dapagliflozin improves the health of people with type 1 diabetes when taken with insulin.

## **What kind of study was this?**

This was a “single-blind” study. This means the researchers knew what participants were taking, but the participants did not.

In this study, participants took dapagliflozin with insulin or a placebo with insulin. 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.

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?

You visited the study site 6 times.

Before the study started, the study doctors did a physical examination to make sure you could join the study. They also took blood and urine samples and checked your heart health using an electrocardiogram, also called an ECG.

**During the study**, participants took 1 of 3 treatments once a day for 7 days. All 3 treatments included insulin taken as an injection. In the 3 treatment groups, the insulin was taken with a pill containing a low dose of dapagliflozin, a high dose of dapagliflozin, or the placebo.

## What were the study results?

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 website listed at the end of this summary. If a full report of the study results is available, it can also be found on this website.

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 act in the body?

Researchers wanted to learn how dapagliflozin acted in the body when it was combined with an insulin injection.

So, they measured:

- the average amount of dapagliflozin in the blood
- the highest amount of dapagliflozin in the blood
- how long it took for dapagliflozin to reach its highest amount in the blood

Researchers did not study these measurements for the participants who took the placebo.

In general, researchers found that the average and highest amounts of dapagliflozin in the blood were highest when participants took the high dose of dapagliflozin with insulin.

After taking dapagliflozin combined with insulin once a day for 7 days, it took between 1 to 3 hours for both dapagliflozin doses to reach their highest amount in the blood.

### How did dapagliflozin affect the body?

Researchers wanted to learn how the different dapagliflozin doses affected the body when it was combined with an insulin injection. So, they measured how much blood sugar left the body through urine. Researchers compared these sugar levels before treatment to the levels after 7 days of treatment.

Participants who took the 2 different dapagliflozin doses had similar increases in the sugar levels in their urine after 7 days of treatment.

## What medical problems did the participants have?

The medical problems participants have during clinical studies that the doctors think might be related to the study drugs are called “adverse reactions”. An adverse reaction is considered “serious” when it is life threatening, causes lasting problems, or requires hospital care.

The adverse reactions that happen in a study may or may not be caused by the study drugs. A lot of research is needed to know whether a drug causes an adverse reaction.

The adverse reactions that happened in this study are not in this summary. Because there was a very small number of participants, leaving this information out helps protect their identities. The website listed at the end of this summary may have more information about the adverse reactions that happened in this study.

## How has this study helped patients and researchers?

These results helped researchers learn how dapagliflozin combined with insulin acts in patients with type 1 diabetes, how the combination affects the body, and if dapagliflozin is safe to take with insulin.

The results presented here are for a single study. 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.

## Where can I learn more about this study?

You can find more information about this study on the website listed below. If a full report of the study results is available, it can also be found here.

- [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Once you are on the website, type “**NCT02582840**” into the search box called “**Other Terms**”. Then, click “**Search**”.

**The full title of your study is:** A clinical pharmacology and long-term study to evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of dapagliflozin therapy in combination with insulin in Japanese subjects with type 1 diabetes who have inadequate glycemic control

**The protocol number of your study is:** D1695C00001 (Part A)

AstraZeneca K.K. sponsored this study and has headquarters at 1800 Concord Pike, Wilmington, DE 19850.

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.



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.

CISCRP • One Liberty Square, Suite 510 • Boston, MA 02109

1-877-MED-HERO • [www.ciscrp.org](http://www.ciscrp.org)