EMPA-VISION: A study that looks at the function of the heart in patients with heart failure who take empagliflozin

Boehringer Ingelheim

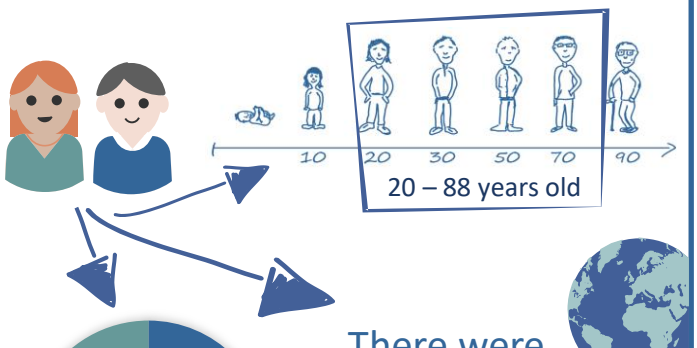
In **chronic heart failure**, the heart does not work as well as it should. This means the heart is unable to pump enough blood to the rest of the body.

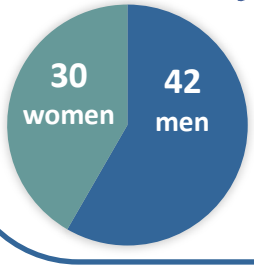
This **STUDY** was done to find out:

Does a medicine called **empagliflozin** change the way the heart muscle uses energy?

Participants...

- had chronic heart failure for at least 3 months





There were **72 participants** from the **United Kingdom.**

Each day, participants took:

1 10 mg empagliflozin

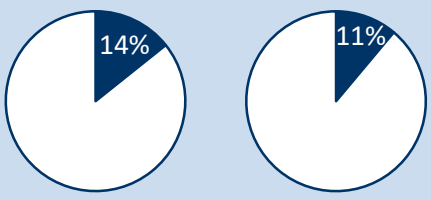
or

1 placebo, *which didn't contain any medicine*

RESULTS

After 12 weeks, the way the heart muscle uses energy **was not different** between the empagliflozin group and the placebo group.

14% of the empagliflozin group and **11%** of the placebo group had **unwanted effects**.



5 out of 35 participants

4 out of 36 participants

Study: 1245-0148

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This is a summary of results from 1 clinical study.

We thank all study participants. You helped us to answer important questions about empagliflozin and the treatment of heart failure.

What was this study about?

The purpose of this study was to find out how a medicine called empagliflozin helps people with chronic heart failure.

In chronic heart failure, the heart does not work as well as it should. This means the heart is unable to pump enough blood to the rest of the body. People with chronic heart failure often find it difficult to exercise or take care of daily activities. New medicines are therefore needed to improve quality of life for people with chronic heart failure.

Empagliflozin is a medicine that helps people with type 2 diabetes to lower their blood sugar. Empagliflozin has also been tested in people with a certain type of chronic heart failure. It was shown that empagliflozin lowered the chance of being admitted to hospital for heart failure or dying from a cardiovascular cause.

In this study, we wanted to find out whether empagliflozin changes the way the heart muscle uses energy.

Who took part in this study?

People could take part in this study if they were 18 years or older and had chronic heart failure for at least 3 months.

A total of 72 people took part in the study. The study included 42 men (58% of participants) and 30 women (42% of participants). The average age was 68 years. The youngest participant was 20 years old and the oldest participant was 88 years old. This study was done in the United Kingdom.

People with 2 types of chronic heart failure were included. One type is called heart failure with reduced ejection fraction. In these people, the percentage of blood leaving the heart with each beat is 40% or less. The other type is called heart failure with preserved ejection fraction. In these people, the percentage of blood leaving the heart with each beat is 50% or more.

How was this study done?

Participants were divided into 2 groups of almost equal size. Every participant had an equal chance of being in each group. The groups were:

- Empagliflozin group: participants took 1 tablet of 10 mg empagliflozin per day
- Placebo group: participants took 1 tablet of placebo per day

Placebo tablets looked like empagliflozin but did not contain any medicine. We compared empagliflozin with placebo to find out how well empagliflozin works.

Participants and doctors did not know in which group the participants were.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health. Doctors used magnetic resonance spectroscopy (MRS) to see how the heart muscle uses energy (measured as the PCr/ATP ratio). We wanted to know whether study treatment for 12 weeks changes the way the heart muscle uses energy. The results were compared between the treatment groups.

What were the results of this study?

Some assessments could not be done. This was because we did not want to put participants at risk by asking them to come in for visits during the COVID-19 pandemic.

After 12 weeks, the way the heart muscle uses energy (measured as the PCr/ATP ratio) was not different between the empagliflozin group and the placebo group. This was true in both heart failure with reduced ejection fraction and heart failure with preserved ejection fraction.

Did participants have any unwanted effects?

Yes, participants in both treatment groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by empagliflozin or placebo. In this study, 5 out of 35 participants (14%) in the empagliflozin group had unwanted effects. 4 out of 36 participants (11%) in the placebo group had unwanted effects. The only unwanted effect that occurred in more than 1 participant was itchy skin (pruritus).

Unwanted effects were serious if the doctor thought they were serious for any reason. In this study, 1 participant (3%) in the empagliflozin group had a serious unwanted effect. 1 participant (3%) in the placebo group had a serious unwanted effect.

Where can I find more information about this study?

You can find further information about this study at these websites:

1. Go to http://www.mystudywindow.com and search for the study number 1245.148.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2017-000376-28.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03332212.

Boehringer Ingelheim sponsored this study.

The full title of the study is: EMPA-VISION: A randomised, double-blind, placebo-controlled, mechanistic cardiac magnetic resonance study to investigate the effects of empagliflozin treatment on cardiac physiology and metabolism in patients with heart failure

This was a Phase 3 study. This study started in March 2018 and finished in May 2020.

Are there additional studies?

If we do more clinical studies with empagliflozin, you will find them on the websites listed above. To search for these studies, use the word empagliflozin or BI 10773.

Important notice

This lay summary is provided as part of Boehringer Ingelheim's commitment to publicly share clinical study results.

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Other studies may have different results. Usually, more than one study is carried out to find out how well a medicine works and to determine the side effects of a medicine.

This lay summary may include uses, formulations, or treatment regimens for the medicine studied that may be approved or not approved in your country. This lay summary is not intended to promote any product or indication, to guide treatment decisions, or to replace the advice of a healthcare professional.

You should not change your therapy based on the results of this study. Always consult with your treating physician about your therapy.