EMPERIAL: A study to test how empagliflozin affects the distance that people with chronic heart failure (HF preserved EF) can walk in 6 minutes

(1245-0167)

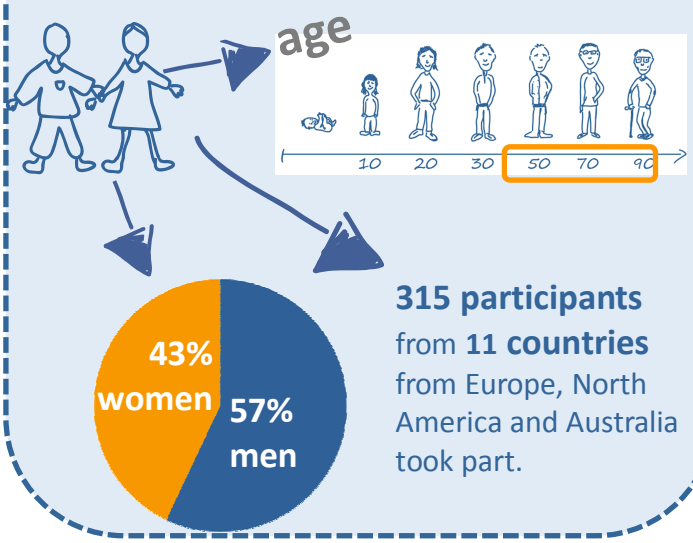
Boehringer Ingelheim

Chronic heart failure is a serious illness. People with chronic heart failure have difficulties in exercising and taking care of daily activities.

This **study** was to find out:

Does **empagliflozin** help people with **chronic heart failure?** This was tested by measuring how **far they can walk** in 6 minutes.

Participants who took part had chronic heart failure with ejection fraction of more than 40% (HF preserved EF)



315 participants from **11 countries** from Europe, North America and Australia took part.

Each participant took each day

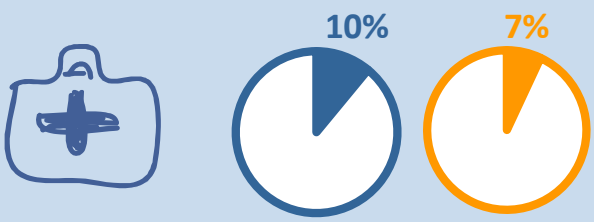
1 10 mg empagliflozin

or

1 placebo

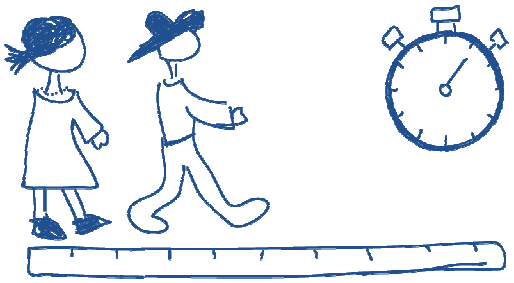
which didn't contain any medicine

10% of participants who took empagliflozin and 7% of participants who took placebo had **unwanted effects.**



RESULTS

After 12 weeks of treatment, there was no difference between the two treatment groups in the distance the participants walked.



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This is a summary of results from one clinical study.

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

What was this study about?

The purpose of this study was to find out whether 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. A study in people with type 2 diabetes and cardiovascular disease showed that taking empagliflozin lowered the chances of having to go to hospital because of heart failure. Researchers think that empagliflozin might also help people with chronic heart failure, whether or not they have diabetes.

In this study, we wanted to find out whether empagliflozin helps people with chronic heart failure to walk further in 6 minutes. We included people with chronic heart failure who had an ejection fraction of more than 40%. This is called chronic heart failure with preserved ejection fraction.

Who took part in this study?

Adult patients with chronic heart failure with ejection fraction more than 40% could participate in this study.

A total of 315 participants were treated in the study. There were 179 men (57% of participants) and 136 women (43% of participants). The average age was 74 years. The youngest participant was 36 years old and the oldest participant was 92 years old.

The following table shows the numbers of participants in the study in different countries:

Region	Countries	Number of participants
Europe	Germany, Greece, Italy, Norway, Poland, Portugal, Spain, Sweden	189
North America	Canada, United States	124
Australia	Australia	2

How was this study done?

The 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 empagliflozin 10 mg per day for 12 weeks
- Placebo group: participants took 1 tablet of placebo per day for 12 weeks

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

The participants and doctors did not know who was in the empagliflozin group or who was in the placebo group. Participants visited the doctors regularly. During these visits, the doctors collected information about the participant's health.

To see whether empagliflozin helps people with chronic heart failure to exercise, the participants did a walking test. Each participant had to walk as far as they could in exactly 6 minutes.

The participants first did the walking test at the start of the study, before they took any study treatment. They also did the walking test during the study and at the end of the study. We compared the distance each participant could walk before and after 12 weeks of taking study medicine.

What were the results of this study?

The results showed that taking empagliflozin for 12 weeks did not improve walking distance. Patients in the empagliflozin group walked on average 10 metres more than they did at the start of the study. Patients in the placebo group walked on average 5 metres more than they did at the start of the study. We did statistical tests on the results. We found that it was likely that the difference between the treatment groups came about by chance. This means it was probably not affected by empagliflozin. These results do not mean that empagliflozin is not effective at all in people with heart failure. Other studies are being done to find out if empagliflozin is effective in treating chronic heart failure. These studies look at whether empagliflozin reduces the risk of death or having to go to hospital for heart failure.

Did participants have any unwanted effects?

Yes, participants in both groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by empagliflozin or placebo. In this study, 16 out of 157 participants (10%) in the empagliflozin group had unwanted effects. 11 out of 158 participants (7%) in the placebo group had unwanted effects.

The table below shows the most common unwanted effects. The table also shows how many participants had each of these unwanted effects.

Type of unwanted effect	**Empagliflozin** **157 participants were in this group**	**Placebo** **158 participants were in this group**
Low blood pressure (hypotension)	4 participants (3%)	1 participant (less than 1%)
Urinary tract infection	1 participant (less than 1%)	2 participants (1%)
Bladder infection (cystitis)	No participants	2 participants (1%)

Some unwanted effects were serious because they required a visit to hospital, were life-threatening, or the doctor thought they were serious for any other reason. In this study, 1 participant (less than 1%) in the empagliflozin group and 2 participants (1%) in the placebo group had serious unwanted effects.

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.trials.boehringer-ingelheim.com/ and search for the study number **1245-0167**.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number **2017-004072-59**.
3. Go to www.clinicaltrials.gov and search for the NCT number **NCT03448406**.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A phase III randomised, double-blind trial to evaluate the effect of 12 weeks treatment of once daily EMPagliflozin 10 mg compared with placebo on ExeRcise ability and heart failure symptoms, In patients with chronic HeArt FaiLure with preserved Ejection Fraction (HFpEF) (EMPERIAL – preserved)'

This study started in April 2018 and finished in October 2019.

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 words **empagliflozin** and **BI 10773**.

Important notice

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

You should not change your therapy based on the results of this study without first talking to your treating physician. Always consult your treating physician about your specific therapy.

Boehringer Ingelheim has provided this lay summary in accordance with European Union transparency obligations.