EMPEROR-Reduced: A study to test whether empagliflozin is effective in people with chronic heart failure with reduced ejection fraction

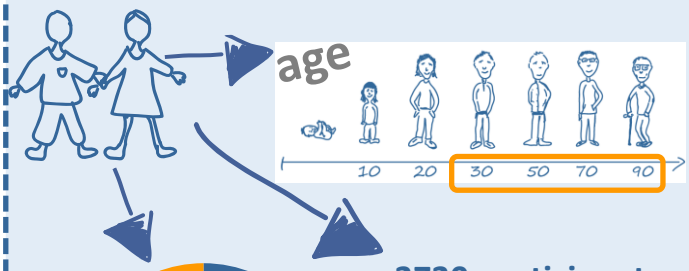
Boehringer Ingelheim

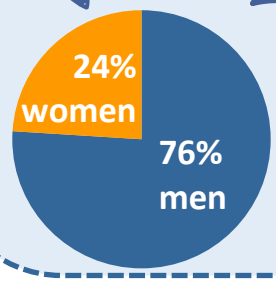
Chronic heart failure is a serious illness that usually gets worse over time.

This **study** was to find out:

Does **empagliflozin** lower the chances of having to go to hospital for heart failure or dying of cardiovascular cause?

Participants who took part had chronic heart failure with ejection fraction of 40% or lower (reduced ejection fraction)





3730 participants from **20 countries** all over the world took part.

Half of the participants took every day

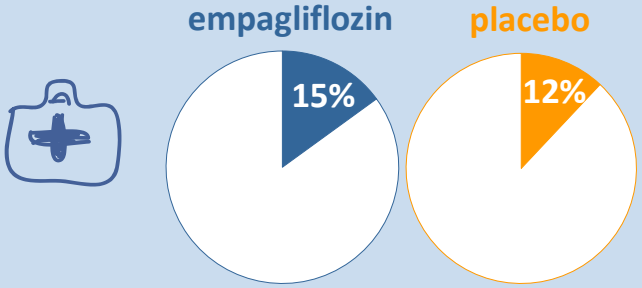
1 10 mg empagliflozin

Half of the participants took every day

1 placebo

which didn't contain any medicine

15% of participants who took empagliflozin and 12% of participants who took placebo had **unwanted effects**.



RESULTS

Empagliflozin lowered the chance of being admitted to **hospital** for heart failure or **dying** due to cardiovascular cause **by 25%.**

Study: 1245-0121

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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. Chronic heart failure often gets worse over time. People with chronic heart failure may need to be hospitalised for their condition. Some people with chronic heart failure may eventually die from their condition. New medicines are therefore needed 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 lowers the chances of patients having to go to hospital for heart failure or dying from a cardiovascular cause. We included people with chronic heart failure who had an ejection fraction of 40% or lower. Ejection fraction is the percentage of blood in the main chamber of the heart that is pumped out with each beat. An ejection fraction of 40% or lower is called reduced ejection fraction.

Who took part in this study?

Adults with chronic heart failure with ejection fraction 40% or lower could participate in this study. A total of 3730 participants took part in the study. There were 2837 men (76% of participants) and 893 women (24% of participants). The average age was 67 years. The youngest participant was 25 years old and the oldest participant was 94 years old.

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

Region	Countries	Number of Participants
Europe	Poland, Netherlands, Hungary, Germany, Czech Republic, Italy, France, Spain, United Kingdom, Belgium	1353
Latin America	Brazil, Argentina, Mexico	1286
Asia	Japan, China, South Korea	493
North America	United States, Canada	425
Other	India, Australia	173

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
- 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 in people with heart failure.

The participants and doctors did not know who was in the empagliflozin group or who was in the placebo group. Patients in this study took empagliflozin or placebo tablets for slightly over 14 months on average. Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health. We wanted to know how many patients had to go to hospital because of heart failure or who died from a cardiovascular cause.

What were the results of this study?

In the placebo group, 462 out of 1867 participants (24.7%) had to be admitted to hospital for heart failure or died from a cardiovascular cause. In the empagliflozin group, 361 out of 1863 participants (19.4%) had to be admitted to hospital for heart failure or died from a cardiovascular cause. These results show that empagliflozin lowered the chance of being admitted to hospital for heart failure or dying from a cardiovascular cause by 25% compared with placebo.

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, 283 out of 1863 participants (15%) in the empagliflozin group had unwanted effects. 227 out of 1863 participants (12%) in the placebo group had unwanted effects.

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

Type of unwanted effect	**Empagliflozin** **1863 participants were in this group** 	**Placebo** **1863 participants were in this group** 
Low blood pressure (hypotension)	43 participants (2%) 	34 participants (2%) 
Urinary tract infection	27 participants (1%) 	26 participants (1%) 
Kidney problems (renal impairment)	27 participants (1%) 	20 participants (1%) 
Low blood sugar (hypoglycaemia)	17 participants (1%) 	21 participants (1%) 
Dehydration	11 participants (1%) 	1 participant (less than 1%) 

Some unwanted effects were serious because they required a stay in hospital or a longer stay in hospital, were life-threatening, or fatal. Unwanted effects were also serious if they led to disability, or the doctor thought they were serious for any other reason. In this study, 51 participants (3%) in the empagliflozin group had serious unwanted effects. 51 participants (3%) 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 **1245-0121**.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number **2016-002280-34**.
3. Go to www.clinicaltrials.gov and search for the NCT number **NCT03057977**.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A phase III randomised, double-blind trial to evaluate efficacy and safety of once daily empagliflozin 10 mg compared to placebo, in patients with chronic Heart Failure with reduced Ejection Fraction (HFrEF)'

This study started in April 2017 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 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.