This was a study in healthy volunteers

This study in healthy people tested whether taking a low strength of empagliflozin, linagliptin, and metformin together in 1 pill is the same as taking them in separate pills

This is a summary of results from one clinical study.

We thank all volunteers who took part in this study. You helped to answer important questions about the combination of empagliflozin, linagliptin, and metformin.

What was this study about?

The purpose of this study was to find out about the amount of 3 different medicines (empagliflozin, linagliptin, and metformin) in the blood. We wanted to know if the amount is different if they are taken as separate tablets or as combination tablets.

Why was this study needed?

Before testing a new medicine in patients, we need to know how the body processes the medicine. Studies in healthy people can help us answer this question.

Empagliflozin, linagliptin, and metformin might be taken together. A new combination tablet contains all 3 of these medicines. We wanted to know about the new combination tablets. Are they taken up by the body in the same way as when each medicine is taken as separate tablets?

Which medicines were studied?

We studied the medicines called empagliflozin, linagliptin, and metformin. These are all medicines that can help to lower blood sugar in patients with type 2 diabetes.

All 3 medicines are taken as tablets that patients swallow. The combination of all 3 medicines is also taken as a tablet that patients swallow. The metformin was extended release in both types of tablets.

Who took part in this study?

A total of 30 healthy people took part in the study. This included 19 men and 11 women. The youngest participant was 24 years old and the oldest participant was 55 years old.

This study was done in Germany.

How was this study done?

All participants were to receive the empagliflozin, linagliptin, and metformin as separate tablets and also as combination tablets. The participants were divided into 2 groups.

One group started by taking separate tablets of 10 mg empagliflozin, 5 mg linagliptin, and 500 mg metformin as a single dose. Then they switched to take combination tablets of the same amounts of each medicine, again as a single dose. The other group started by taking the combination tablets, and then switched to take the separate tablets. The participants had to wait at least 35 days between taking the separate tablets and taking the combination tablets.

The participants and doctors knew which tablets of medicine the participants were taking.

We wanted to find out how much of each of the medicines (empagliflozin, linagliptin, and metformin) was in the blood. We also wanted to know the highest amount of each medicine in the blood. To find out, the doctors took blood at different times before and after participants took the medicines. The blood samples were collected after they took the separate tablets and after the combination tablets.

What were the results of this study?

This study showed that the amount of each medicine (empagliflozin, linagliptin, and metformin) in the blood was about the same if taken as separate tablets or as combination tablets.

Did the participants have any unwanted effects?

Yes, participants had unwanted effects while taking the medicines as separate tablets and as combination tablets. Unwanted effects are any health problems that the doctors think were caused by empagliflozin, linagliptin, or metformin.

During this study, 7 out of 29 participants (24%) had unwanted effects while taking the medicines as combination tablets. 6 out of 30 participants (20%) had unwanted effects while taking the medicines as separate tablets.

The table below shows the unwanted effects.

Unwanted effect	**Empagliflozin, linagliptin, metformin - combination (29 people)**	**Empagliflozin, linagliptin, metformin - separate (30 people)**
Nausea	4 people (14%)	3 people (10%)
Headache	4 people (14%)	2 people (7%)
Decreased appetite	1 person (3%)	2 people (7%)
Vomiting	1 person (3%)	1 person (3%)
Diarrhoea	1 person (3%)	1 person (3%)

None of the unwanted effects were serious.

Where can I find more information about this study?

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

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number 1361.11**.**
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2018-001266-42.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03629054.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'Bioequivalence of a low strength fixed dose combination tablet of empagliflozin/linagliptin/metformin extended release compared to the free combination of empagliflozin, linagliptin, and metformin extended release tablets following oral administration in healthy male and female subjects (an open-label, randomised, single-dose, two-period, two-sequence crossover study)'.

This was a Phase I study. This study started in September 2018 and finished in November 2018.

Are there additional studies?

If we do more clinical studies with empagliflozin, linagliptin, and metformin you will find them on the websites listed above. To search for these studies, use the words empagliflozin, linagliptin, and metformin.

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.