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## A study to investigate BI 1026706 in patients with diabetic macular edema

This is a summary of a clinical study in diabetic macular edema (DME). It is written for the general public. It includes information about how researchers did the study and what the results were.

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We thank all patients who took part in this study. Through your participation, you helped researchers answer important questions about BI 1026706 and the treatment of DME.

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### What was this study about?

Researchers wanted to find out whether a medicine called BI 1026706 helps patients with DME. Macular edema occurs when fluid builds up in a part of the eye called the macula. The excess fluid causes the macula to swell. Swelling of the macula leads to loss of vision. DME is a complication of type 1 or type 2 diabetes.

This study started in June 2016 and finished in October 2017.



### Why was the study needed?

New treatments for DME are needed. Some treatments are already available for DME. These treatments are given as injections directly into the eye. Injections into the eye are uncomfortable and might cause complications. Researchers want to develop new treatments for DME that can be given without injections. This study was done to test a new medicine called BI 1026706. This medicine can be taken as a tablet by mouth, and no injections are needed.



### Which medicines were studied?

BI 1026706 is a new medicine that is being tested for treating DME. It is taken as a tablet by mouth.

Placebo tablets looked like BI 1026706 but did not contain any medicine. Researchers compared BI 1026706 with placebo to find out how well BI 1026706 works.



## Who participated in the study?

Patients could take part in this study if they had DME with mild vision loss.

Overall, 105 patients took part in the study. They were 77 men and 28 women. The average age was 63 years. The youngest patient was 41 years old. The oldest patient was 86 years old.

The table below shows the number of patients in each country.

| Country  | Number of Patients | Country        | Number of Patients |
|----------|--------------------|----------------|--------------------|
| Germany  | 23 patients        | Spain          | 11 patients        |
| France   | 19 patients        | Hungary        | 10 patients        |
| Greece   | 15 patients        | United Kingdom | 7 patients         |
| Portugal | 14 patients        | Belgium        | 6 patients         |



## How was this study done?

The patients were divided into 2 groups. One group of patients received BI 1026706 and the other group received placebo for 12 weeks. Every patient had an equal chance of being in the BI 1026706 group or in the placebo group. The patients did not know which treatment they were taking. The doctors did not know either.

Patients in the BI 1026706 group took a tablet of 100 milligrams BI 1026706 twice a day. Patients in the placebo group took a placebo tablet twice a day.

Researchers wanted to know if BI 1026706 could help to reduce swelling in the macula. To measure the amount of swelling, study doctors measured the thickness of the macula. They did this by taking special pictures of each patient's macula. Researchers measured the thickness of each patient's macula at the beginning of the study and at the end of the study.

Patients visited their doctors regularly. During the visits, the doctors also collected information on each patient's health.



## What were the results of this study?

BI 1026706 and placebo did not have any meaningful effect on the thickness of the macula. In other words, BI 1026706 did not reduce swelling in the macula of patients with DME.



## Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study, 7 out of 52 patients (14%) in the BI 1026706 group and 7 out of 53 patients (13%) in the placebo group had unwanted effects. Each unwanted effect was reported for no more than 1 patient in either treatment group.

Some unwanted effects were serious because they required a visit to the hospital or a longer stay in the hospital. In this study, there was 1 patient in the BI 1026706 group who had serious unwanted effects. No patients in the placebo group had serious unwanted effects.



## Are there follow-up studies?

No follow-up studies are planned.

If more clinical studies with BI 1026706 are done, they may be found on the public websites listed in the section below. To search for these studies, use the following names: BI 1026706.



## Where can I find more information?

You can find the scientific summaries of the study results at these websites:

[www.trials.boehringer-ingelheim.com](http://www.trials.boehringer-ingelheim.com) search for the study number: 1320.22

[www.clinicaltrialsregister.eu/ctr-search](http://www.clinicaltrialsregister.eu/ctr-search) search for the EudraCT number: 2015-003529-33

[www.clinicaltrials.gov](http://www.clinicaltrials.gov) search for the NCT number: NCT02732951

The sponsor of this study was Boehringer Ingelheim.

The full title of the study is:

‘A randomised, double-masked, placebo-controlled exploratory study to evaluate pharmacodynamics, safety, and tolerability of orally administered BI 1026706 for 12 weeks in patients with mild visual impairment due to centre-involved diabetic macular oedema (DME)’.

This was a Phase 2a study.

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### 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.

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