A study that tests BI 1467335 in patients with diabetic eye disease (diabetic retinopathy). It looks at the way BI 1467335 is taken up, the effects it has, and how well it is tolerated.

Boehringer Ingelheim

Diabetic eye disease

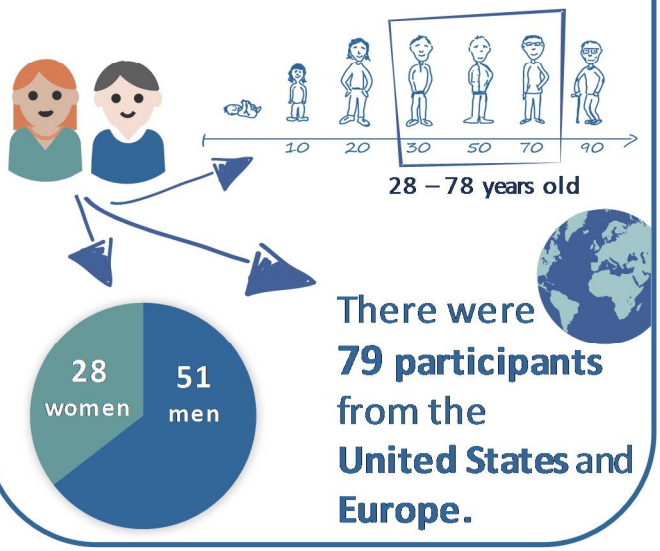
(diabetic retinopathy) affects tiny blood vessels inside the retina. This can lead to vision impairment or even blindness.

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

→ Can people with **diabetic eye disease** tolerate a medicine called **BI 1467335**?

Participants...

✓ had type 1 or type 2 diabetes with non-proliferative diabetic retinopathy



There were **79 participants** from the **United States** and **Europe.**

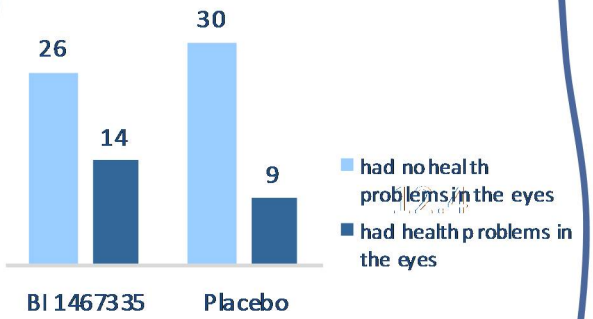
Each day, for 3 months, participants took:

2 5 mg BI 1467335 → 10 mg group

or

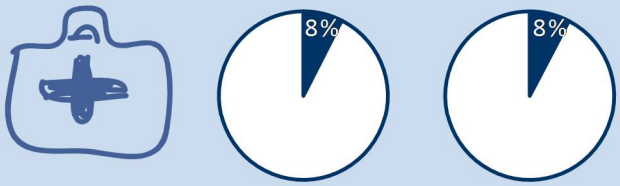
2 placebo, *which didn't contain any medicine*

RESULTS



After 6 months, 14 out of 40 participants (35%) in the BI 1467335 group and 9 out of 39 participants (23%) in the placebo group developed at least one health problem in their eyes.

8% of the BI 1467335 group and **8%** of the placebo group had **unwanted effects.**



3 out of 40 participants

3 out of 39 participants

Study: 1386.12

A study that tests BI 1467335 in patients with diabetic eye disease (diabetic retinopathy). It looks at the way BI 1467335 is taken up, the effects it has, and how well it is tolerated.

This is a summary of results from 1 clinical study.

We thank all study participants. You helped us to answer important questions about BI 1467335 and the treatment of diabetic retinopathy.

What was this study about?

The purpose of this study was to find out whether people with diabetic eye disease (diabetic retinopathy) can tolerate a medicine called BI 1467335.

Diabetes can damage several organs, including the eyes. Diabetic retinopathy affects tiny blood vessels inside the retina (the tissue lining the back of the eye). This can lead to vision impairment or even blindness. New treatments are needed for this condition. BI 1467335 is being developed to treat it.

This study also tested whether BI 1467335 helps to improve the symptoms of diabetic retinopathy. Because this was not the focus of the study, we did not include the results in this summary.

Who took part in this study?

Adults with type 1 or type 2 diabetes who had non-proliferative diabetic retinopathy could participate in this study. They could not participate if they had a condition called centre-involved diabetic macular oedema.

79 participants took part in this study. 51 (65%) were men and 28 (35%) were women. The youngest participant was 28 years old, and the oldest participant was 78 years old. The average age was 53 years.

The following table shows the numbers of participants in the study in different regions.

Region	Countries	Number of Participants
North America	United States	62
Europe	Austria, Norway, Portugal, Spain, United Kingdom	17

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:

- BI 1467335 group: participants took 2 tablets of 5 mg BI 1467335 per day for about 3 months
- Placebo group: participants took 2 tablets of placebo per day for about 3 months

Placebo tablets looked like BI 1467335 tablets but did not contain any medicine. The participants and doctors did not know whether the participants were in the BI 1467335 group or in the placebo group.

In this study, we wanted to find out how well the participants tolerated BI 1467335. To find out, we compared how many participants in each group developed health problems in their eyes.

Participants were in the study for about 6 months. During this time, they visited the doctors regularly. At these visits, the doctors collected information about the participants' health.

What were the results of this study?

After about 6 months, 14 out of 40 participants (35%) in the BI 1467335 group developed at least 1 health problem in their eyes. 9 out of 39 participants (23%) in the placebo group developed at least 1 health problem in their eyes.

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 BI 1467335 or placebo.
In this study, 3 out of 40 participants (8%) in the BI 1467335 group had unwanted effects.
3 out of 39 participants (8%) in the placebo group had unwanted effects.

Unwanted effects are serious if they require a stay in hospital, a longer stay in hospital, or are life-threatening. Unwanted effects are also serious if the doctor thinks they are serious for any other reason. In this study, 1 participant (3%) in the BI 1467335 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 1386.12.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2016-002971-91.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03238963.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A Randomized, double-masked, placebo-controlled exploratory study to evaluate safety, tolerability, pharmacodynamics and pharmacokinetics of Orally administered BI 1467335 for 12 weeks with a 12 week follow up period in patients with Nonproliferative diabetic retinopathy without center-involved diabetic macular edema (ROBIN study)'.

This was a Phase IIa study. This study started in November 2017 and finished in May 2020.

Are there additional studies?

We stopped developing BI 1467335 for the treatment of diabetic retinopathy, so no further studies are planned.

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.