A study to test different doses of BI 1467335 in patients with NASH (1386-0004)

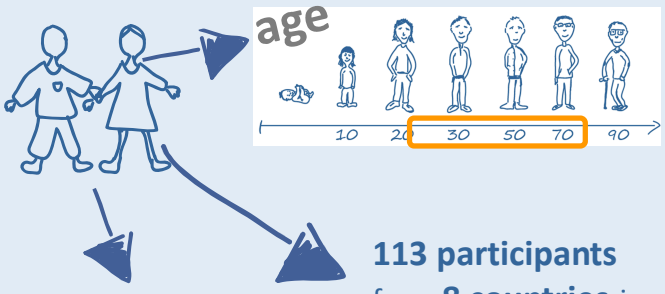
Boehringer Ingelheim

NASH stands for **n**on-**a**lcoholic **s**teato-**h**epatitis. Excess fat in the liver causes **inflammation and scarring**.

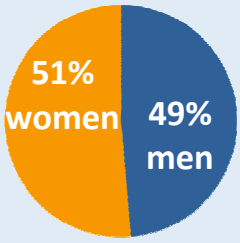
This **study** was to find out:

Can **BI 1467335** block an enzyme that is involved in inflammation? Which is the **best dose**?

Participants who took part had NASH



113 participants from **8 countries** in **Europe and North America** took part.



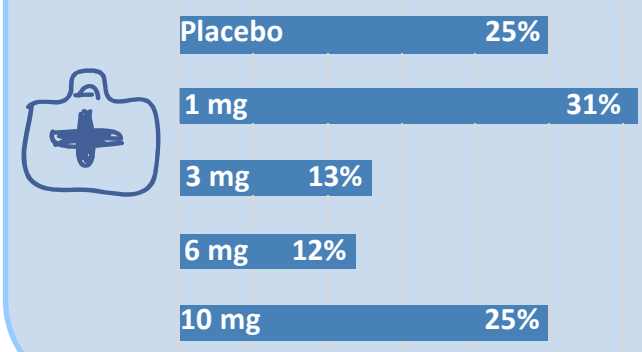
There were five groups. Participants took each day

- BI 1467335 in one of the following doses: 1 mg / 3 mg / 6 mg / 10 mg

or

- Placebo, *which looked like BI 1467335 but didn't contain any medicine*

Participants in all groups had **unwanted effects**. None of them were serious.



RESULTS

BI 1467335 reduced the enzyme activity in the liver **more than placebo**. We calculated that a dose of **3.45 mg** a day would be sufficient to reduce the enzyme activity by 90%.

A study to test different doses of BI 1467335 in patients with NASH

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about BI 1467335 and the treatment of non-alcoholic steato-hepatitis (NASH).

What was this study about?

The purpose of this study was to find out whether a medicine called BI 1467335 could help people with NASH. NASH is a build-up of fat in the liver that causes inflammation and scarring. If there is a lot of scarring, the liver may stop working. We tested different doses of BI 1467335.

Who took part in this study?

Adults with NASH could participate in this study. People with other forms of liver disease could not participate.

113 participants took part in this trial. 58 were women and 55 were men. The youngest participant was 21 years old and the oldest participant was 74 years old. The average age was 51 years.

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

Region	Countries	Number of Participants
Europe	Belgium, France, Germany, the Netherlands, Spain, United Kingdom	51
North America	Canada, United States	62

How was this study done?

Each participant took BI 1467335 or placebo once a day for 12 weeks. Placebo tablets looked like BI 1467335 but did not contain any medicine.

The participants were divided into 5 groups. The groups were:

- 1 mg of BI 1467335
- 3 mg of BI 1467335
- 6 mg of BI 1467335
- 10 mg of BI 1467335
- Placebo

Participants and doctors did not know in which group the participants were.

We wanted to find out if BI 1467335 blocks an enzyme in the liver that is involved in inflammation. To figure this out, we checked whether the enzyme's activity in participants' blood changed after 12 weeks of treatment.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health.

What were the results of this study?

This study found that BI 1467335 reduces enzyme activity in participants' blood more than placebo. Higher doses of BI 1467335 reduced the activity of the enzyme more than lower doses. We calculated that a dose of 3.45 mg a day would reduce the activity of the enzyme by 90% after 12 weeks.

Did participants have any unwanted effects?

Yes, participants in all groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by BI 1467335 or placebo. In this study:

- 8 out of 32 participants (25%) in the placebo group had unwanted effects.
- 5 out of 16 participants (31%) in the 1 mg BI 1467335 group had unwanted effects.
- 2 out of 16 participants (13%) in the 3 mg BI 1467335 group had unwanted effects.
- 2 out of 17 participants (12%) in the 6 mg BI 1467335 group had unwanted effects.
- 8 out of 32 participants (25%) in the 10 mg BI 1467335 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	Placebo 32 participants were in this group	1 mg BI 1467335 16 participants were in this group	3 mg BI 1467335 16 participants were in this group	6 mg BI 1467335 17 participants were in this group	10 mg BI 1467335 32 participants were in this group
Nausea	1 participant (3%)	2 participants (13%)	0 participants	0 participants	3 participants (9%)
Fatigue	1 participant (3%)	0 participants	0 participants	0 participants	2 participants (6%)
Rash	0 participants	0 participants	0 participants	0 participants	2 participants (6%)
Headache	2 participants (6%)	1 participant (6%)	0 participants	1 participant (6%)	0 participants

None of the unwanted effects were serious. This means that the unwanted effects did not lead to a hospital stay, that they were not life-threatening, and that they did not lead to a disability.

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 1386-0004.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2016-000499-83.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03166735.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A multi-centre, double-blind, parallel-group, randomised, placebo-controlled phase IIa study to investigate safety, tolerability, pharmacodynamics, and pharmacokinetics of different doses of orally administered BI 1467335 during a 12-week treatment period compared to placebo in patients with clinical evidence of NASH'.

This study started in July 2017 and finished in June 2019.

Are there additional studies?

If we do more clinical studies with BI 1467335, you will find them on the websites listed above. To search for these studies, use the word BI 1467335. No further studies with BI 1467335 in people with NASH are currently planned.

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.