A study to find out how well healthy people and people with cystic fibrosis tolerate BI 443651

This is a summary of results from one clinical study.

We thank everyone who took part in this study. You helped to answer important questions about BI 443651.

What was this study about?

The purpose of this study was to find out how well healthy people and people with cystic fibrosis tolerate BI 443651 compared with placebo. BI 443651 was being developed to treat diseases of the lungs and airways.

This study had 2 parts, and each part is described separately in the following sections.

Who took part in this study?

Part 1: healthy participants

40 healthy men were in this part of the study. The youngest participant was 19 years old and the oldest participant was 55 years old.

This part of the study was done in the United Kingdom.

Part 2: participants with cystic fibrosis

People with cystic fibrosis could enrol in this part of the study. 24 people took part. This included 16 men and 8 women. The youngest participant was 22 years old and the oldest participant was 55 years old.

This part of the study was done in the United Kingdom and Germany.

How was this study done?

In this study, participants had to inhale BI 443651 or placebo from a special inhaler called a Respimat® inhaler. The placebo inhaler looked like the BI 443651 inhaler but did not contain any medicine.

Part 1: healthy participants

We wanted to find out how people tolerate different doses of BI 443651. To do this, we looked at the number of participants with health problems that occurred during treatment. These are any health problems that begin after participants start taking the medicine, whether doctors think they are caused by the study medicine or not.

The participants were given different doses of BI 443651. The first participants received a low dose and participants who started the study later received higher doses. Participants took between 100 micrograms (µg) and 1800 µg of BI 443651 twice a day.

Participants knew which BI 443651 dose they were assigned to take. However, they did not know if they were taking placebo or BI 443651. The doctors did not know this either. Every participant had 4 times the chance of taking BI 443651 compared to placebo.

Treatment lasted 6.5 days.

Part 2: participants with cystic fibrosis

We also wanted to find out how well people with cystic fibrosis tolerate BI 443651. We looked at the number of participants with health problems that occurred during treatment in this part of the study as well.

All participants received both BI 443651 and placebo, but not at the same time. The participants were divided into 2 groups. 1 group started by taking BI 443651 for 13.5 days. Then they switched to take placebo for 13.5 days. The other group started by taking placebo for 13.5 days. Then they switched to take BI 443651 for 13.5 days. The participants had to wait at least 30 days between switching treatments.

Participants took 1 dose of 600 µg BI 443651 twice a day or 1 dose of placebo twice a day. Participants and doctors did not know if the participants took placebo or BI 443651.

What were the results of this study?

Participants in both parts of the study had health problems that occurred during treatment.

Part 1: healthy participants

- 27 out of 32 participants (84%) in the BI 443651 groups had health problems that occurred during treatment.
- 3 out of 8 participants (38%) in the placebo group had health problems that occurred during treatment.

Participants who took higher doses of BI 443651 had more health problems than those taking the lowest dose or placebo.

Part 2: participants with cystic fibrosis

- 13 out of 22 participants (59%) had health problems that occurred during treatment with BI 443651.
- 14 out of 24 participants (58%) had health problems that occurred during treatment with placebo.

Did the participants have any unwanted effects?

Yes, participants in both parts of the study had unwanted effects. Unwanted effects are any health problems that the doctors think were caused by the study medicines. This means that the unwanted effects are a subset of the health problems discussed in the previous section.

Part 1: healthy participants

17 out of 32 participants (53%) in the BI 443651 groups had unwanted effects.
12 participants had changes in the sense of taste (dysgeusia) and 10 participants had a cough.
None of the unwanted effects were serious.

No participants in the placebo group had unwanted effects.

Participants who took the lowest dose of BI 443651 or placebo did not have any unwanted effects. Participants taking at least 400 µg of BI 443651 experienced unwanted effects. As the doses increased, there were more unwanted effects.

Part 2: participants with cystic fibrosis

4 out of 22 participants (18%) had unwanted effects while taking BI 443651. The following unwanted effects affected 1 participant each: chest discomfort, cough, coughing up blood (haemoptysis), and ringing or buzzing in the ears (tinnitus). None of the unwanted effects were serious.

No participants in the placebo group had unwanted effects.

Where can I find more information about this study?

The study number is BI 1363.2 and the EudraCT number for this study is 2016-001504-31. For more information about the study, go to www.clinicaltrials.gov and search for the NCT number NCT02976519.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A Phase Ib, multicentre, double blind, randomised, two-part study, first part multiple rising dose and second part two-way cross-over, to assess safety, tolerability, efficacy and pharmacokinetics of BI 443651 compared to placebo via Respimat® in healthy volunteers and cystic fibrosis subjects'.

This study started in February 2017 and finished in August 2018.

Are there additional studies?

If we do more clinical studies with BI 443651, you will find them on the website listed above. To search for these studies, use the word BI 443651.

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.