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## A study of the effects of BI 443651 on the lung function of patients with asthma

This is a summary of a clinical study in asthma. It describes how researchers did the study and what the results were. We have written this summary for the general public.

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We thank all patients who took part in this study. You helped researchers answer important questions about BI 443651 and the treatment of airway diseases.

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### What was this study about?

Researchers wanted to find out whether a medicine called BI 443651 affects the lung function of patients with asthma.



### Why was this study needed?

BI 443651 is being developed to help patients with diseases of the lungs and airways. Researchers need to study how BI 443651 works in patients with asthma. This will help them to understand how BI 443651 works in patients with other diseases of the lungs and airways.



### Which medicines were studied?

Researchers studied the medicine BI 443651. It is being developed to treat diseases of the lungs and airways. In this study, patients had to inhale BI 443651 from a special inhaler called a Respimat® inhaler.

Researchers compared different doses of BI 443651 with placebo. A placebo looks like BI 443651 but does not contain any medicine. The placebo was also inhaled from a Respimat® inhaler.



### Who took part in this study?

Patients with mild asthma could take part in this study. Some patients were already taking other medicine to treat their asthma before they started the study.

Overall, 37 patients took part in this study. There were 34 men and 3 women. The average age was 37 years. The youngest patient was 23 years old and the oldest patient was 59 years old. This study was done in the United Kingdom.



## How was this study done?

This study tested 3 different doses of BI 443651. The doses were 100 µg BI 443651, 400 µg BI 443651, and 1200 µg BI 443651. Each dose of BI 443651 was inhaled from a RespiMat® inhaler. The study also tested a placebo.

All patients took every dose of BI 443651 and also placebo, but not at the same time. They took each dose of BI 443651 or placebo for 2 days. In between, patients had to wait for 2 to 4 weeks before they took another dose of BI 443651 or the placebo. At any time, the patients did not know if they were taking BI 443651 or placebo, or which dose they were taking.

During the study, researchers checked the lung function of the patients. They used a test called a methacholine challenge test. The patients first had to take a medicine called methacholine. Then the patients had to blow as hard as they could into a machine. The machine measured how much air the patients could forcefully breathe out in 1 second (FEV<sub>1</sub>). Researchers wanted to find out if BI 443651 had an effect on the results of this test.

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



## What were the results of this study?

The effects of the methacholine challenge test were no different when patients were taking different doses of BI 443651 or placebo, or when they were taking no study medication.



## Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study:

- 15 patients (43%) had unwanted effects while taking 100 µg BI 443651.
- 21 patients (58%) had unwanted effects while taking 400 µg BI 443651.
- 26 patients (72%) had unwanted effects while taking 1200 µg BI 443651.
- 3 patients (9%) had unwanted effects while taking placebo.

None of the unwanted effects were serious.

The unwanted effects seen in more than 1 patient while taking any of the treatments are shown in the table below.

	BI 443651				Placebo (35 patients)
	100 µg dose (35 patients)	400 µg dose (36 patients)	1200 µg dose (36 patients)		
Cough	14 patients (40%)	10 patients (28%)	14 patients (39%)	3 patients (9%)	
Bad taste in mouth (dysgeusia)	5 patients (14%)	12 patients (33%)	15 patients (42%)	0 patients	
Chest discomfort	0 patients	1 patient (3%)	10 patients (28%)	0 patients	



## Are there additional studies?

If researchers do additional clinical studies with BI 443651, you will find them on the websites listed in the next section. To search for these studies, use the following name: BI 443651.



## Where can I find more information about this study?

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

1. Go to <http://www.trials.boehringer-ingelheim.com/> and search for the study number 1363.7.
2. Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search for the NCT number NCT03135899.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A 2-part phase I, multiple-dose, single- and double-blind randomised, double-dummy, placebo-controlled, 4-way crossover study to assess safety and tolerability of BI 443651 via Respimat® versus placebo via Respimat® in subjects with mild asthma following methacholine challenge'.

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

## 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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