

# A study to test whether different doses of BI 425809 improve mental functioning in people with schizophrenia

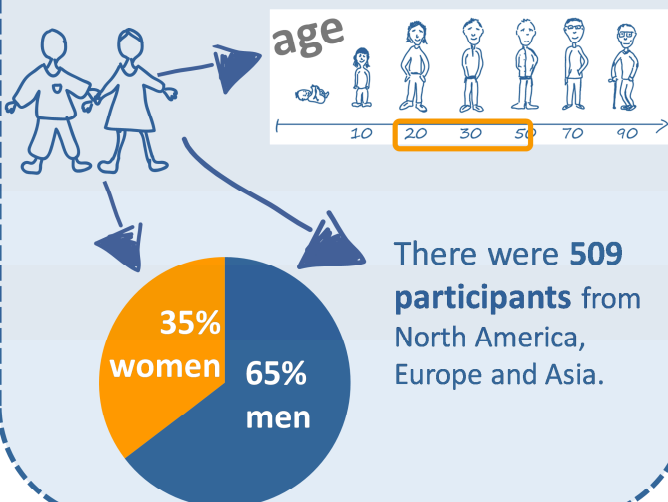
BI 425809 is a medicine that is being developed to treat people with **disorders of the brain**.

This **study** was to find out:








Do different doses of **BI 425809** help people with schizophrenia to **improve** their mental functioning?

## The participants were adults with schizophrenia



Each participant took each day

-  2 mg BI 425809
- or
-  5 mg BI 425809
- or
-  10 mg BI 425809
- or
-  25 mg BI 425809
- or
-  Placebo

Between **14% and 21%** of participants taking the different doses of BI 425809 had unwanted effects.

**17%** of participants taking placebo had unwanted effects.



## RESULTS

Some doses of BI 425809 <sup>12.4</sup> helped participants to **improve** their mental functioning.

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## A study to test whether different doses of BI 425809 improve mental functioning in people with schizophrenia

This is a summary of results from one clinical study.

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We thank all study participants. You helped us to answer important questions about BI 425809 and the treatment of mental functioning in schizophrenia.

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### What was this study about?

The purpose of this study was to find out whether a medicine called BI 425809 helps people with schizophrenia. BI 425809 is a medicine that is being developed to treat people with disorders of the brain. When we develop a new medicine, we need to make sure it works. We wanted to see if different doses of BI 425809 help people with schizophrenia to improve their mental functioning.



### Who took part in this study?

Adults with schizophrenia could participate in this study.

509 participants took part in this study. 329 (65%) were men and 180 (35%) were women. The youngest participant was 18 years old and the oldest participant was 50 years old. The average age was 37 years.

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

Region	Number of Participants
North America	221
Europe	152
Asia	136



## How was this study done?

The participants were divided into 5 groups:

- 2 mg BI 425809
- 5 mg BI 425809
- 10 mg BI 425809
- 25 mg BI 425809
- Placebo

The participants and doctors did not know what each participant was receiving. Placebo tablets looked like BI 425809 tablets but did not contain any medicine.

We compared BI 425809 with placebo to find out how well BI 425809 works. We measured this by doing tests to check participants' mental functioning. We did these tests before participants started taking BI 425809 or placebo and after they took it for 12 weeks. Then we compared the scores to see if there was a difference in mental functioning.

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



## What were the results of this study?

We found that some doses of BI 425809 worked better than placebo to improve mental functioning. The higher doses worked better than the lower doses.




























## 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 425809 or placebo. In this study:

- 18 out of 85 participants (21%) who took 2 mg BI 425809 had unwanted effects.
- 15 out of 84 participants (18%) who took 5 mg BI 425809 had unwanted effects.
- 14 out of 85 participants (17%) who took 10 mg BI 425809 had unwanted effects.
- 12 out of 85 participants (14%) who took 25 mg BI 425809 had unwanted effects.
- 29 out of 170 participants (17%) who took placebo 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	BI 425809				Placebo
	2 mg (85 people) 	5 mg (84 people) 	10 mg (85 people) 	25 mg (85 people) 	Placebo (170 people) 
Headache	2 people (2%) 	4 people (5%) 	6 people (7%) 	5 people (6%) 	5 person (3%) 
Sleepiness (somnolence)	2 people (2%) 	4 people (5%) 	5 people (6%) 	2 people (2%) 	3 people (2%) 
Dizziness	4 people (5%) 	2 people (2%) 	1 person (1%) 	2 people (2%) 	3 people (2%) 
Constipation	1 person (1%) 	0 people 	0 people 	2 people (2%) 	1 person (1%) 

Some unwanted effects were serious because they required a stay in hospital, a longer stay in hospital, or were life-threatening. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, 1 participant (1%) in the BI 425809 2 mg group had serious unwanted effects, 1 participant (1%) in the BI 425809 5 mg group had serious unwanted effects, and 2 participants (1%) in the placebo group had serious unwanted effects.

## 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 1346.9.
2. Go to [www.clinicaltrialsregister.eu/ctr-search](http://www.clinicaltrialsregister.eu/ctr-search) and search for the EudraCT number 2016-000285-28.
3. Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search for the NCT number NCT02832037.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A phase II randomized, double-blinded, placebo-controlled parallel group trial to examine the efficacy and safety of 4 oral doses of BI 425809 once daily over 12 week treatment period in patients with Schizophrenia'.

This study started in September 2016 and finished in January 2020.



## Are there additional studies?

If we do more clinical studies with BI 425809, you will find them on the websites listed above. To search for these studies, use the term **BI 425809**.

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## 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.

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