A study in people with Alzheimer's disease to test whether BI 425809 improves their thinking abilities and memory

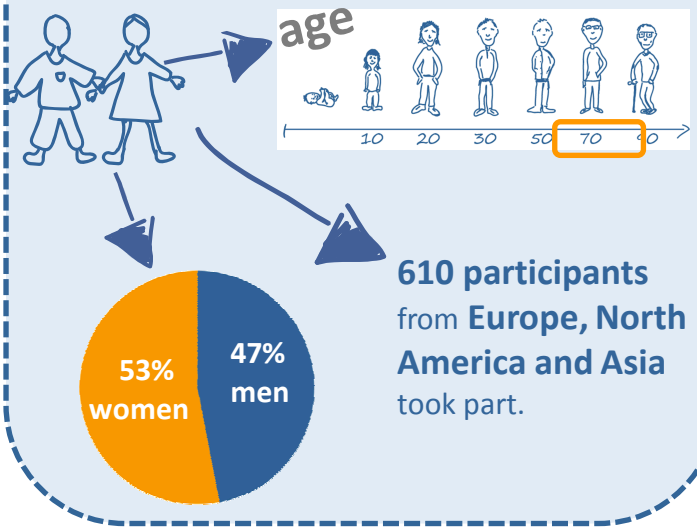
Boehringer Ingelheim

New medicines are needed to **help improve thinking and memory** in people with **Alzheimer's disease**.

This **study** was to find out:

Does a medicine called **BI 425809** help people with **Alzheimer's disease**?

Participants who took part had a loss of memory due to Alzheimer's disease



610 participants from **Europe, North America and Asia** took part.

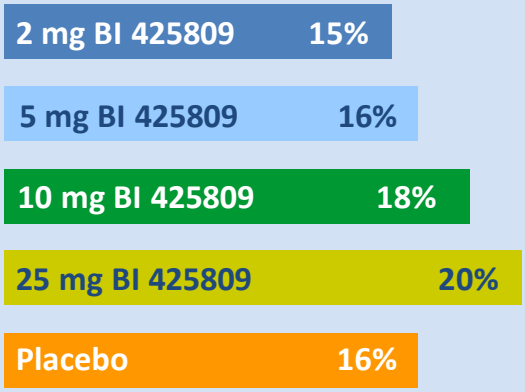
There were five groups. Participants took each day

1 2 / 5 / 10 / 25 mg BI 425809

or

1 Placebo
which didn't contain any medicine

Participants in all groups had **unwanted effects**.



RESULTS

After 12 weeks of treatment, participants who took BI 425809 **had similar test scores** compared with participants who took placebo.

Study: 1346.23

A study in people with Alzheimer's disease to test whether BI 425809 improves their thinking abilities and memory

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about BI 425809 and the treatment of Alzheimer's disease.

What was this study about?

The purpose of this study was to find out whether a medicine called BI 425809 helps people with Alzheimer's disease. People with Alzheimer's disease have difficulties with many thinking functions, such as attention, memory, problem solving, and planning. New medicines are needed to help improve thinking and memory in people with Alzheimer's disease.

Who took part in this study?

People who were 55 years old or older with a loss of memory and some difficulties with thinking due to Alzheimer's disease could take part in this study.

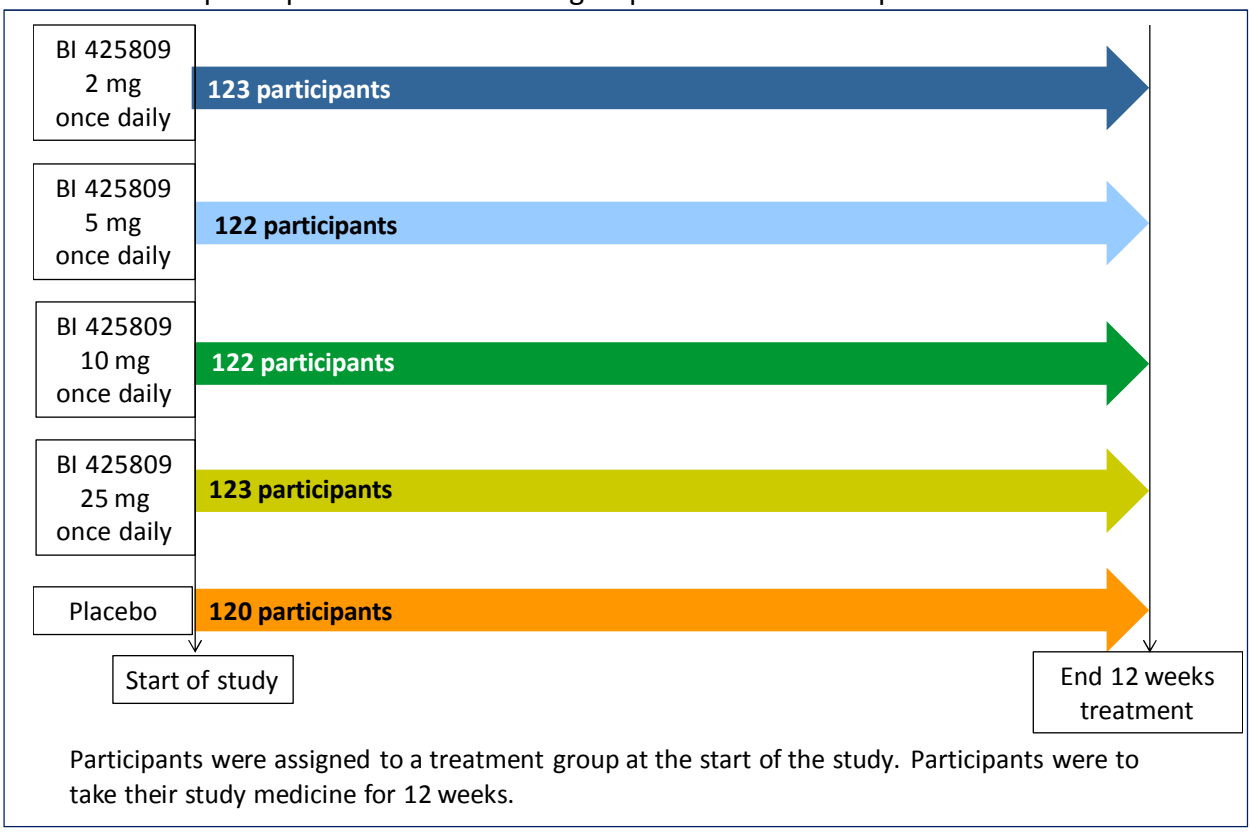
Overall, 610 people took part in this study. There were 286 men and 324 women. The average age was 73 years. The youngest participant was 55 years old and the oldest participant was 89 years old.

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

Region	**Countries**	**Number of Participants**
Europe	Austria, Finland, France, Germany, Greece, Hungary, Italy, Norway, Poland, Spain, United Kingdom	370
North America	Canada, United States	186
Asia	Japan	54

How was this study done?

Study participants were divided into 5 groups. Four of the groups took BI 425809 at different doses. One group took placebo tablets. Participants took BI 425809 tablets or placebo tablets for 12 weeks. Placebo tablets looked like BI 425809 but did not contain any medicine. Participants and doctors did not know in which group the participants were. The dose and the number of participants treated in each group are shown in the picture below.



Participants were assigned to a treatment group at the start of the study. Participants were to take their study medicine for 12 weeks.

We compared different doses of BI 425809 with placebo to find out how well BI 425809 works. Study participants took a special test called the ADAS-Cog_{11}. This test measures speaking, memory, awareness, and problem solving. Changes in the total test score over time were measured. We looked at the results of the tests after 12 weeks of taking BI 425809 or placebo.

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

What were the results of this study?

After 12 weeks of treatment, participants who took BI 425809 had similar test scores as participants who took placebo. We did statistical tests on the results. We found no difference between any of the BI 425809 and placebo treatment groups.

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 the BI 425809 2 mg group, 19 out of 123 participants (15%) had unwanted effects.
- In the BI 425809 5 mg group, 20 out of 122 participants (16%) had unwanted effects.
- In the BI 425809 10 mg group, 22 out of 122 participants (18%) had unwanted effects.
- In the BI 425809 25 mg group, 24 out of 123 participants (20%) had unwanted effects.
- In the placebo group, 19 out of 120 participants (16%) 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 (123 people)	5 mg (122 people)	10 mg (122 people)	25 mg (123 people)	Placebo (120 people)
Dizziness	3 people (2%)	5 people (4%)	0 people	5 people (4%)	1 person (1%)
Diarrhoea	1 person (1%)	4 people (3%)	2 people (2%)	4 people (3%)	3 people (3%)
Nausea	4 people (3%)	1 person (1%)	0 people	4 people (3%)	1 person (1%)
Reduced amount of red blood cells (haemo-globin decreased)	0 people	1 person (1%)	1 person (1%)	4 people (3%)	0 people
Headache	3 people (2%)	5 people (4%)	3 people (3%)	3 people (2%)	2 people (2%)

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital, or were life-threatening. Unwanted effects were also serious if they led to disability or the doctor thought they were serious for any other reason. 1 participant in the 2 mg BI 425809 group and 2 participants 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 1346.23.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2015-005438-24.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02788513.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A multi-centre, double-blind, parallel-group, randomised controlled study to investigate efficacy and safety of orally administered BI 425809 during a 12-week treatment period compared to placebo in patients with cognitive impairment due to Alzheimer's Disease'.

This was a Phase 2 study. This study started in August 2016 and finished in October 2019.

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 word BI 425809.

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.