A study to test whether BI 409306 improves mental abilities in people with mild Alzheimer's disease and difficulties with mental functioning

This is a summary of a clinical study in Alzheimer's disease. It is written for the general public. It includes information about how researchers did the study and what the results were.

We thank all people who took part in this study. Through your participation, you helped researchers answer important questions about BI 409306 and the treatment of Alzheimer's disease.

What was this study about?

Researchers wanted to find out whether BI 409306 helped people with mild Alzheimer's disease. The researchers also wanted to find the dose of BI 409306 that worked the best for these people.

Mild Alzheimer's disease is when a person is having some problems with memory and thinking. They may be losing the ability to do activities that have several steps. These people can still carry out simple daily activities by themselves.

This study started in March 2015 and finished in October 2017.

Why was the study needed?

New medicines to treat people with mild Alzheimer's disease are needed. Currently approved medicines are used to treat the symptoms of mild Alzheimer's disease. No treatment has yet been shown to help slow the progression of the disease.

Which medicines were studied?

BI 409306 is a new medicine that is being tested for treating mild Alzheimer's disease. It blocks a protein called phosphodiesterase 9 (PDE9A). Blocking this protein might help to improve memory and learning in people with mild Alzheimer's disease. BI 409306 is taken as a tablet by mouth.

Placebo tablets looked like BI 409306 but did not contain any medicine. Researchers compared BI 409306 with placebo to find out how well BI 409306 works.

Who participated in the study?

This study included people with mild Alzheimer's disease who were 55 years old or older.

On average, study participants had received their diagnosis of Alzheimer's disease 1.5 years before the study started. Each participant had a study partner who helped to provide information about the participant.

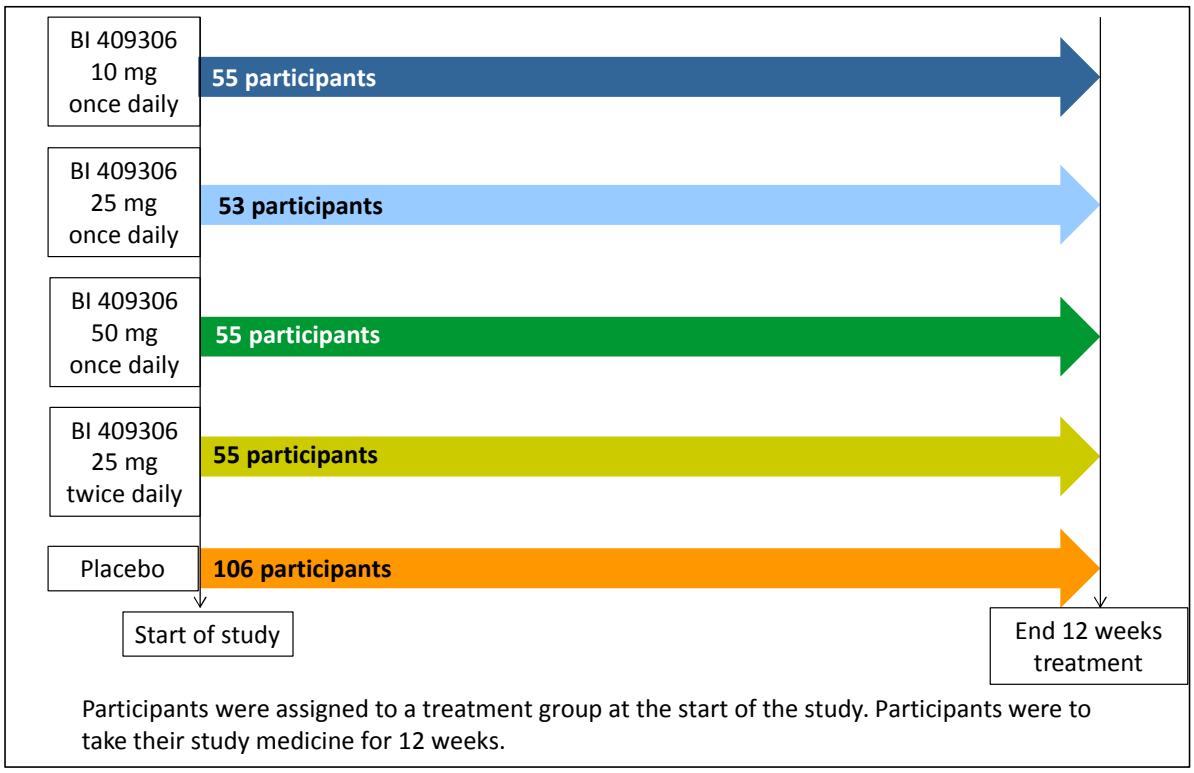
Overall, 329 participants received treatment in this study. The average age was 74 years. Most of the participants (86%) were older than 65 years. The youngest participant was 55 years old. The oldest participant was 91 years old. Half of the participants (50%) were men and half (50%) were women.

Most of the participants were from Europe (257 participants from Austria, Belgium, France, Germany, Italy Netherlands, Poland, Portugal, and United Kingdom). 72 participants were from North America (Canada and United States).

How was this study done?

Study participants were divided into 5 groups. Four of the groups took BI 409306 at different doses. One group took placebo tablets. Participants took BI 409306 tablets or placebo tablets for 12 weeks. The participants did not know which treatment they were taking. The doctors did not know either. The dose and the number of participants treated in each group are shown in the picture on the next page.

At the beginning of the study, 5 participants were also assigned to receive an approved Alzheimer's disease treatment called donepezil. After the study had started, there was a change in the way the study was done. No more participants were assigned to receive donepezil. The 5 participants who were already assigned continued to take donepezil. Because of the low number of participants in this group, no conclusions about this treatment can be drawn.



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

Study participants took a set of special tests called the Neuropsychological Test Battery (NTB) a few times during the study. These tests measure thinking speed, attention, learning, memory, and problem solving. Changes in the total test score over time were measured. These measurements can show changes in the ability of people with Alzheimer's disease to think clearly and accurately. The researchers looked at the results of the tests after 12 weeks of taking BI 409306 or placebo.

Study participants visited their doctors regularly. During the visits, the doctors collected information on each participant's health.

What were the results of this study?

After 12 weeks of treatment, participants who took BI 409306 had similar test scores as participants who took placebo. Researchers used statistical tests on the results. They found no difference between any of the BI 409306 and placebo treatment groups.

Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In total, 29 out of 329 participants (9%) from all treatment groups had unwanted effects.

Unwanted effects reported by more than 1 participant are listed in the table below.

	BI 409306				
	10 mg (55 people)	**25 mg (53 people)**	**50 mg (55 people)**	**25 mg twice/day (55 people)**	**Placebo (106 people)**
Seeing flashes of light (photopsia)	0 people	1 person (2%)	1 person (2%)	1 person (2%)	0 people
Vision blurred	1 person (2%)	0 people	1 person (2%)	1 person (2%)	0 people
Headache	0 people	2 people (4%)	0 people	0 people	0 people
Dizziness	0 people	1 person (2%)	1 person (2%)	0 people	0 people

Are there follow-up studies?

If more clinical studies with BI 409306 are done, they may be found on the public websites listed in the section below. To search for these studies, use the following name: BI 409306.

Where can I find more information?

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

www.trials.boehringer-ingelheim.com	search for the study number: 1289.7
www.clinicaltrialsregister.eu	search for the EudraCT number: 2013-005040-28
www.clinicaltrials.gov	search for the NCT number: NCT02337907

The sponsor of this study was Boehringer Ingelheim.

The full title of the study is:

'A multi-centre, double-blind, parallel-group, randomised controlled study to investigate efficacy, safety and tolerability of orally administered BI 409306 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.

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.