

A study to test whether BI 409306 improves mental abilities in people with early-stage Alzheimer's disease

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 early-stage Alzheimer's disease. Early-stage Alzheimer's disease is when a person is having some problems with memory and thinking. They are still able to carry out daily functions by themselves. The researchers also wanted to find the dose of BI 409306 that worked the best for these people.

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



Why was the study needed?

New medicines to treat people with early-stage Alzheimer's disease are needed. People with early-stage Alzheimer's disease will probably develop Alzheimer's disease in the next 10 years. By the time these people are diagnosed with Alzheimer's disease, they are no longer able to care for themselves. Currently approved medicines are used to treat the symptoms of Alzheimer's disease. None are available to treat people in the early stage.



Which medicines were studied?

BI 409306 is a new medicine that is being tested for treating early-stage Alzheimer's disease. It blocks a protein called phosphodiesterase 9 (PDE9A). Blocking this protein might help to improve memory and learning in people with early-stage 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 early-stage Alzheimer's disease who were 55 years old or older. They had not yet received any treatment for their Alzheimer's disease before entering this study. Each participant had a study partner who helped to provide information about the participant.

The study planned for 288 people to take part. Because it took too long to find enough participants, the study was stopped early. At the time the final analysis was done, 128 participants had finished the treatment. The average age was 73 years. Most of the participants (89%) were older than 65 years. The youngest participant was 58 years old. The oldest participant was 88 years old. About half of the participants (45%) were men and half (55%) were women.

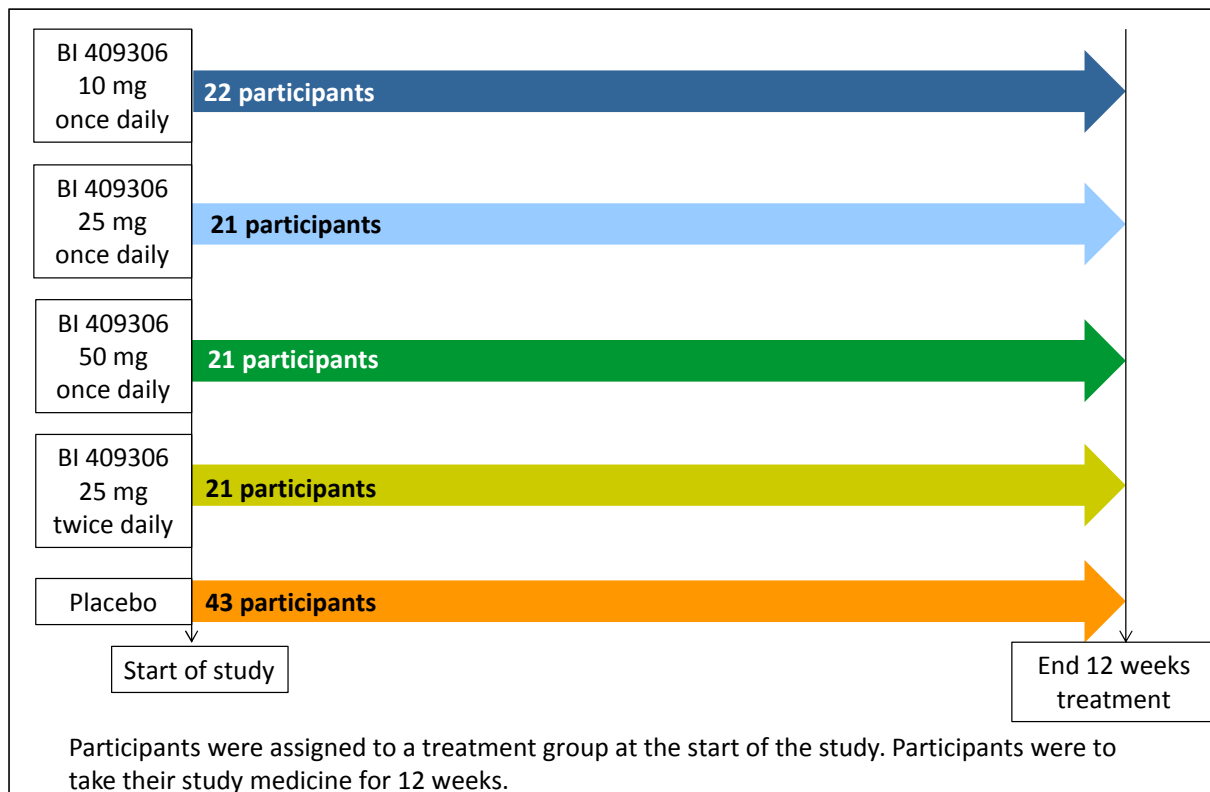
Most of the participants were from Europe (110 participants from Austria, France, Germany, Italy, Netherlands, Poland, Portugal, Spain, and United Kingdom). 18 participants were from North America (Canada and United States).



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.



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, 16 out of 128 participants (13%) from all treatment groups had unwanted effects.

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

	BI 409306				Placebo (43 people)
	10 mg (22 people)	25 mg (21 people)	50 mg (21 people)	25 mg twice/day (21 people)	
Vision blurred	0 people	0 people	2 people (10%)	0 people	0 people
Visual impairment	0 people	0 people	1 person (5%)	0 people	1 person (2%)
Headache	0 people	1 person (5%)	1 person (5%)	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: 1289.5

www.clinicaltrialsregister.eu search for the EudraCT number: 2013-005031-24

www.clinicaltrials.gov search for the NCT number: NCT02240693

The sponsor of this study was Boehringer Ingelheim.

The full title of the study is:

‘A multi-centre, double-blind, parallel-group, randomized controlled study to investigate the efficacy, safety and tolerability of orally administered BI 409306 during a 12-week treatment period compared to placebo in patients with 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.

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