
A study of BI 860585 alone or with exemestane or paclitaxel in patients with different types of cancer

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

We thank all patients who took part in this study. Through your participation, you helped researchers answer important questions about BI 860585 and the treatment of cancer.



What was this study about?

Researchers wanted to know the highest dose of BI 860585 patients could tolerate. To find this dose, researchers looked at how many patients had certain severe health problems that might have been caused by the treatment. They studied BI 860585 given alone and with exemestane or with paclitaxel. Patients in this study had advanced cancer or cancer that had spread. This was the first time BI 860585 was studied in people.

This study started in September 2013 and finished in June 2017. After the highest dose of BI 860585 that patients could tolerate was determined, the study was stopped. This study was stopped early because the sponsor decided not to complete the study.



Why was the study needed?

When a new medicine is discovered, researchers need to learn more about what the best dose is for patients. Patients with advanced cancer often need to take more than one treatment for their cancer. Therefore, researchers needed to find the highest dose of BI 860585 patients could tolerate when taking BI 860585 alone or together with other treatments for cancer.



Which medicines were studied?

Researchers studied the medicine BI 860585. It is being developed to help stop cancer from growing and spreading. BI 860585 is a tablet that patients swallow.

Exemestane is a medicine used to treat breast cancer in women after menopause. It is a tablet that patients swallow.

Paclitaxel is a medicine used to treat some types of cancer. It is given directly into a vein through a needle.



Who participated in the study?

Adult patients with different types of cancer that was advanced or had spread could take part in this study. The patients had to have already taken cancer treatment that was not able to help slow the growth of their cancer.

A total of 90 patients were treated. More patients were planned for the study, but the study was stopped early. 42 patients were men and 48 patients were women. The average age was 61 years. The youngest patient was 20 years old. The oldest patient was 79 years old. Half of the patients were in Belgium and half were in Italy.



How was this study done?

The patients in this study took BI 860585 alone or BI 860585 with another treatment. The treatment each patient took depended on when they started the study and which treatment the doctors thought was best for treating their cancer.

- 41 patients took BI 860585 once a day.
- 25 patients took BI 860585 once a day and exemestane 25 mg once a day.
- 24 patients took BI 860585 once a day. They were also given paclitaxel once a week at the standard approved dose of 60 mg or 80 mg per square metre of body surface area.

Researchers wanted to find the highest dose of BI 860585 that patients could tolerate alone or together with exemestane or paclitaxel during their first cycle of treatment. This dose is called the maximum tolerated dose. One cycle of treatment was 28 days. To find the maximum tolerated dose, researchers looked at how many patients had certain severe health problems that might have been caused by treatment. These are called dose-limiting toxicities.

The patients and their doctors knew which treatment and the dose of BI 860585 they were taking.

As long as a patient did not have a health problem they could not tolerate, they could take their study medicine for as long as their cancer did not grow.

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



What were the results of this study?

During the first cycle of treatment, 4 patients (11%) treated with BI 860585 alone had dose-limiting toxicities. For the patients treated with BI 860585 alone, the maximum tolerated dose of BI 860585 was 220 mg daily.

During the first cycle of treatment, 4 patients (19%) treated with BI 860585 and exemestane had to stop taking study medicine because of health problems. For the patients treated with BI 860585 and 25 mg exemestane, the maximum tolerated dose of BI 860585 was 160 mg daily.

During the first cycle of treatment, 2 patients (11%) treated with BI 860585 and paclitaxel had to stop taking study medicine because of health problems. For the patients treated with BI 860585 and 80 mg per square metre paclitaxel, the maximum tolerated dose of BI 860585 was 160 mg daily.
























Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study, 2 patients (11%) treated with BI 860585 and paclitaxel had to stop taking study medicine because of health problems.

36 out of 41 patients (88%) treated with BI 860585 alone had unwanted effects. 24 out of 25 patients (96%) treated with BI 860585 and exemestane had unwanted effects. All 24 patients treated with BI 860585 and paclitaxel had unwanted effects.

The following table shows the most common unwanted effects seen in at least 40% of patients in any of the treatment groups.

	BI 860585 (41 patients) 	BI 860585 and exemestane (25 patients) 	BI 860585 and paclitaxel (24 patients) 
Too much sugar in the blood (hyperglycaemia)	22 patients (54%) 	9 patients (36%) 	13 patients (54%) 
Diarrhoea	16 patients (39%) 	10 patients (40%) 	14 patients (58%) 
Feeling tired (fatigue)	10 patients (24%) 	9 patients (36%) 	14 patients (58%) 
Mouth sores (stomatitis)	9 patients (22%) 	10 patients (40%) 	7 patients (29%) 
Decreased appetite	9 patients (22%) 	7 patients (28%) 	11 patients (46%) 
Anaemia	1 patient (2%) 	1 patient (4%) 	12 patients (50%) 

Some unwanted effects were serious because they required a visit to or 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, 7 patients (17%) treated with BI 860585 alone had serious unwanted effects. 4 patients (16%) treated with BI 860585 and exemestane had serious unwanted effects. 3 patients (13%) treated with BI 860585 and paclitaxel had serious unwanted effects.

Are there follow-up studies?

No follow-up study is planned.

If more clinical studies with BI 860585 are done, they may be found on the public websites listed in the section below. To search for these studies, use the following names: BI 860585.

 **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: 1325.1

www.clinicaltrials.gov search for the NCT number: **NCT01938846**

The sponsor of this study was Boehringer Ingelheim.

The full title of the study is:

‘An open-label Phase I dose-finding study of BI 860585 administered orally in a continuous dosing schedule as single agent and in combination with exemestane or with paclitaxel in patients with various advanced and/or metastatic solid tumours’.

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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