

INVICTAN-2: A study in people with non-squamous non-small cell lung cancer (nsNSCLC) to find out whether BI 695502 works as well as Avastin® when taken with standard chemotherapy (1302.5)

BI 695502 was developed as a product similar to the approved medicine Avastin®. The combination of Avastin® and chemotherapy has been shown to be effective in previous studies with nsNSCLC.

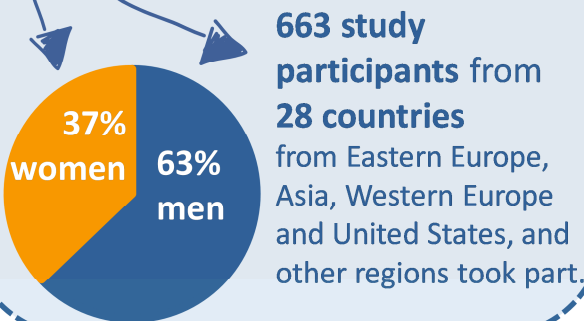
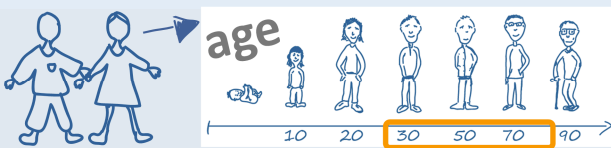
BI 695502 was designed to be very similar to Avastin®. But they are not exactly the same.



This **study** was to find out:

Does BI 695502 together with chemotherapy work as well as Avastin® together with chemotherapy for study participants with nsNSCLC that has returned or spread?

The Study participants were adults with nsNSCLC that has returned or spread



Once every 3 weeks each study participant received an infusion into a vein:



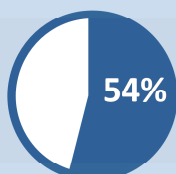
BI 695502 + chemotherapy
OR
Avastin® + chemotherapy

The dose given for all medicines depended on body weight. The chemotherapy for this study was a combination of paclitaxel and carboplatin.

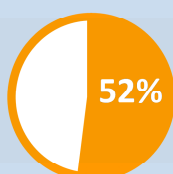
54% of study participants who received BI 695502 and 52% of study participants who received Avastin® had **unwanted effects**.



BI 695502



Avastin®



RESULTS

We found that the effect of BI 695502 with chemotherapy on the tumours was not different from Avastin® with chemotherapy.

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This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about BI 695502 and the treatment of lung cancer.



What was this study about?

The purpose of this study was to compare 2 similar treatments for a type of lung cancer called non-squamous non-small cell lung cancer (nsNSCLC).

Avastin® (bevacizumab) is a medicine that is used to treat nsNSCLC. It is taken in combination with chemotherapy. BI 695502 is a medicine that is designed to be similar to Avastin®. Although BI 695502 and Avastin® are very similar, they are not exactly the same because of the way they are made.

Because BI 695502 and Avastin® are very similar, they should work in a similar way. This study was to find out whether BI 695502 in combination with chemotherapy works as well as Avastin® in combination with chemotherapy.



Who took part in this study?

All patients in this study were adults with recurrent or metastatic nsNSCLC. They were to be eligible for treatment with Avastin® combined with standard chemotherapy.

Overall, 663 patients took part in the study. The study included 417 men (63%) and 246 women (37%). The average age was 61 years. The youngest patient was 27 years old and the oldest patient was 86 years old.

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

Region	Countries	Number of Patients
Asia	Japan, Malaysia, Philippines, South Korea, Thailand, Vietnam	132
Eastern Europe	Bulgaria, Croatia, Hungary, Poland, Romania, Russia, Serbia, Ukraine	322
Western Europe and U.S.	Germany, Greece, Italy, Portugal, Spain, United Kingdom, United States	77
Rest of World	Argentina, Brazil, Chile, Egypt, Mexico, South Africa, Turkey	132



How was this study done?

The patients were divided into 2 groups of almost equal size. One was the BI 695502 with chemotherapy group and the other was the Avastin[®] with chemotherapy group. Every patient had an equal chance of being in the BI 695502 group or in the Avastin[®] group.

Patients and doctors did not know whether the patients were in the BI 695502 group or in the Avastin[®] group.

The chemotherapy for this study was a combination of paclitaxel and carboplatin. This combination is used as a standard treatment for patients with nsNSCLC that has returned or spread.

Patients visited the study site every 3 weeks and received all medicines for their group as infusion into a vein. The dose given for all medicines depended on body weight. Patients received the medicines for as long as they benefited from it or wanted to. After about two and a half years, all patients still in the study switched from BI 695502 to Avastin[®]. We used information only from the time up to this switch for this lay summary.

To compare BI 695502 and chemotherapy with Avastin[®] and chemotherapy, we measured the 'overall response rate'. This is the percentage of patients whose cancer shrinks or disappears after treatment. This was based on images of the tumours taken during treatment up to 18 weeks.

Patients visited the doctors regularly. During these visits, the doctors collected information about the patient's health.



What were the results of this study?













We found that the overall response rate of BI 695502 with standard chemotherapy was not different from Avastin® with standard chemotherapy. This means that BI 695502 works as well as Avastin® when taken with chemotherapy in patients with nsNSCLC.



Did participants have any unwanted effects?

Yes, patients in both groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by BI 695502 or Avastin®. In this study, 181 out of 335 patients (54%) in the BI 695502 group had unwanted effects. 172 out of 328 patients (52%) in the Avastin® group 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.

Unwanted effect	BI 695502		Avastin®	
	335 participants were in this group		328 participants were in this group	
Abnormally high levels of protein in the urine (Proteinuria)	41 patients (12%)		34 patients (10%)	
High blood pressure (Hypertension)	33 patients (10%)		36 patients (11%)	
Nosebleed (Epistaxis)	26 patients (8%)		19 patients (6%)	
Reduced number of red blood cells (Anaemia)	24 patients (7%)		32 patients (10%)	
Nausea	24 patients (7%)		26 patients (8%)	

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital, were life-threatening, or fatal. Unwanted effects were also serious if they led to disability, or the doctor thought they were serious for any other reason. In this study, 42 patients (13%) in the BI 695502 group had serious unwanted effects. 27 patients (8%) in the Avastin® group had serious unwanted effects. 4 patients (1%) in the BI 695502 group died from unwanted effects. 2 patients (1%) in the Avastin® group died from 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 **1302.5**.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number **2014-002161-30**.
3. Go to www.clinicaltrials.gov and search for the NCT number **NCT02272413**.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A multicenter, randomized, double-blind Phase III trial to evaluate efficacy and safety of BI 695502 plus chemotherapy versus Avastin® plus chemotherapy in patients with advanced nonsquamous Non-Small Cell Lung Cancer'.

This study started in July 2015 and finished in November 2018.



Are there additional studies?

If we do more clinical studies with BI 695502, you will find them on the websites listed above. To search for these studies, use the word BI 695502.

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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