A study in patients with metastatic colorectal cancer to test the safety of BI 695502 when given with chemotherapy

This is a summary of a clinical study about cancer. This summary describes the results of the study.

We thank all patients who took part in this study. You helped to answer important questions about BI 695502 and the treatment of cancer.

What was this study about?

The purpose of this study was to find out whether a medicine called BI 695502 is safe to give to patients with metastatic colorectal cancer (mCRC) when combined with chemotherapy.

Why was this study needed?

BI 695502 was being developed as a product similar to the approved medicine Avastin®. The addition of Avastin® to chemotherapy has been shown to be effective in some patients with mCRC. Although BI 695502 and Avastin® are very similar, they are not exactly the same because of the way they are made. Researchers needed to learn more about BI 695502 to see if it is safe for patients.

Which medicines were studied?

BI 695502 is a drug that may slow or stop the growth of certain tumour types by preventing the growth of blood vessels that supply the tumour. In this study, BI 695502 was given as an intravenous infusion (fluid dripped into a vein through a plastic tube and needle).

The combination of the drugs leucovorin, 5-fluorouracil, and oxaliplatin is part of a standard treatment for patients with mCRC. You may hear this combination referred to as 'mFOLFOX6', which is simply a type of chemotherapy. Chemotherapy means that someone is being treated with drugs that help to fight their cancer. The drugs were given as intravenous infusions.

Who took part in this study?

Adult patients with mCRC who had not previously been treated could take part in this study. Only patients who were not candidates for surgery to treat their cancer could be in the trial.

A total of 123 patients took part in the study. This included 68 men (55%) and 55 women (45%). The average age was 58 years. The youngest patient was 22 years old and the oldest patient was 85 years old.

This study was done in Ukraine, the United States, Japan, and Spain. The table below shows the number of patients from each country.

Countries	**Number of Patients**
Ukraine	44
United States	42
Japan	30
Spain	7

How was this study done?

We wanted to find out how safe BI 695502 is. To find out, we looked at the amount of patients who had certain types of health problems after starting to take BI 695502. We compared this to studies on the same health problems that patients had after starting to take Avastin®.

We looked at a certain group of health problems that patients had during the study. Some of the health problems might have been caused by the study medicine. Others might have been caused by something else. The health problems that we looked at are listed in the next section.

Patients came in to the study site every 2 weeks and were given intravenous infusions of all the medicines. The dose given for all medicines depended on body size. Patients remained on treatment for as long as they needed to. After about a year and a half, we switched all patients still in the study from BI 695502 to another drug. We used information only from while they were on BI 695502 for this lay summary.

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

What were the results of this study?

72 out of 123 patients (59%) had at least one of the health problems that we looked for. Most patients (78%) received at least 8 cycles (4 to 5 months) of treatment with BI 695502. We found that number of patients with health problems were similar for BI 695502 and Avastin®.

The table below shows the health problems we looked for.

Health problem	**All patients (123 patients)** 
Allergic reactions (anaphylactic/hypersensitivity/infusion-related reactions)	23 patients (19%) 
Blood clots that lead to other serious health problems (thromboembolic events)	15 patients (12%) 
Holes in the stomach, oesophagus, or intestines (gastrointestinal perforations)	3 patients (2%) 
High blood pressure (hypertension)	35 patients (29%) 
Too much protein in the urine (proteinuria)	12 patients (10%) 
Bleeding in the lungs (pulmonary haemorrhage)	0 patients 
All types of bleeding (all haemorrhages)	28 patients (23%) 
Wound-healing problems (wound-healing complications including abscess and fistulas)	2 patients (2%) 
An illness with headaches, seizures, confusion, and loss of vision (posterior reversible encephalopathy syndrome)	0 patients 
Loss of function in the ovaries (ovarian failure)	0 patients 

Did patients have any unwanted effects?

Yes, patients had unwanted effects. Unwanted effects are any health problems that the doctors think were caused by the study medicines. This means that the unwanted effects are different from the health problems shown on the previous page. In this study, 89 out of 123 (72%) patients had unwanted effects.

The table below shows the 5 most common unwanted effects.

Unwanted effect	**All patients (123 patients)** 
High blood pressure (hypertension)	25 patients (20%) 
Fatigue	21patients (17%) 
Nosebleeds (epistaxis)	16 patients (13%) 
Nausea	16 patients (13%) 
Diarrhoea	15 patients (12%) 

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. In this study, 12 out of 123 patients (10%) had serious unwanted effects.

Where can I find more information about this study?

You can find further information about the study at these websites:

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number 1302.3.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2015-003718-25.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02776683.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A single-arm, open-label, multicenter, multinational, safety and efficacy Phase IIIb trial of BI 695502 plus mFOLFOX6 in patients with previously untreated metastatic colorectal cancer'.

This study started in July 2016 and finished in October 2018.

Are there additional studies?

No further studies are planned.

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.