A study in people with Crohn's disease to find out whether BI 695501 works as well as Humira®

(1297.4)

Boehringer Ingelheim

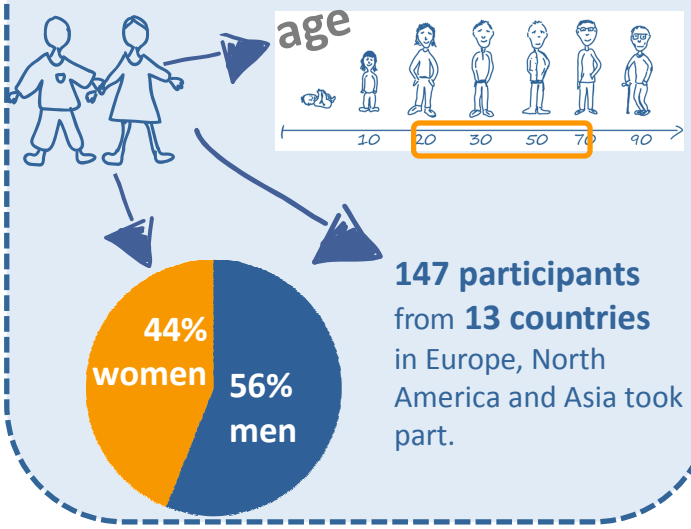
BI 695501 was developed as a product **similar** to the approved medicine **Humira®**. Humira® is effective in **Crohn's disease**.

BI 695501 was designed to be very similar to Humira®. But they are not exactly the same.

This **study** was to find out:

Does **BI 695501** work as well as **Humira®** in Crohn's disease?

Participants who took part had Crohn's disease



147 participants from **13 countries** in Europe, North America and Asia took part.

This study had 2 periods:

Each participant received every 2 weeks

1 Period 1: week 1-22

Humira®

or

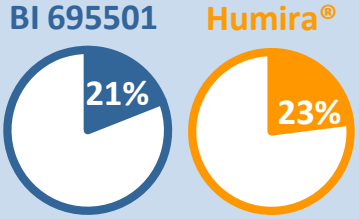
BI 695501

Starting from week 24 all participants received BI 695501.

2 Period 2: week 24-46

BI 695501

During Period 1, 21% of participants who took BI 695501 and 23% of participants who took Humira® had **unwanted effects.**

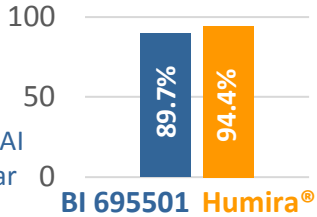


During Period 2, 14% of participants in the BI 695501 group and 15% of participants in the Humira® group had unwanted effects.

RESULTS

BI 695501 works as well as Humira® in the treatment of Crohn's disease.

In both treatment groups, the percentage of participants with decrease of CDAI score ≥70 was similar after 4 weeks.



A study in people with Crohn's disease to find out whether BI 695501 works as well as Humira®

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about BI 695501 and the treatment of Crohn's disease.

What was this study about?

The purpose of this study was to compare 2 similar medicines for Crohn's disease. Crohn's disease causes inflammation of the part of the gastrointestinal tract called the bowel. This can lead to abdominal pain, diarrhoea, fatigue, weight loss, and malnutrition. Crohn's disease can be painful and debilitating.

Humira® (adalimumab) is a medicine that is used to treat Crohn's disease. BI 695501 (Cyltezo®) is a medicine that is designed to be similar to Humira® and is also used to treat Crohn's disease.

Because BI 695501 and Humira® are very similar, they should work in a similar way. This study was to find out whether BI 695501 works as well as Humira®.

Who took part in this study?

People could take part in the study if they were adults with Crohn's disease for 4 months or longer.

Overall, 147 participants took part in the study. The study included 83 men (56%) and 64 women (44%). The average age was 35 years. The youngest participant was 18 years old and the oldest participant was 70 years old.

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

Countries	Number of Participants
Czech Republic	34
Russian Federation	21
Poland	20
United States	18
Ukraine	16
Israel	11
Belarus	7
Croatia	6
Serbia	6
Turkey	4
Bosnia and Herzegovina, Germany, and Greece	4

How was this study done?

The participants were divided into 2 groups of almost equal size. One was the BI 695501 group and the other was the Humira® group. Every participant had an equal chance of being in the BI 695501 group or in the Humira® group.

The participants and doctors did not know whether the participants were in the BI 695501 group or in the Humira® group.

There were 2 periods in the study. During Period 1, the participants were injected with the same dose of BI 695501 or Humira® every 2 weeks for 22 weeks. After 2 weeks, Period 2 started. During Period 2, the participants who received Humira® during Period 1 switched to receive BI 695501 for 22 weeks. This means that all participants received BI 695501 during Period 2.

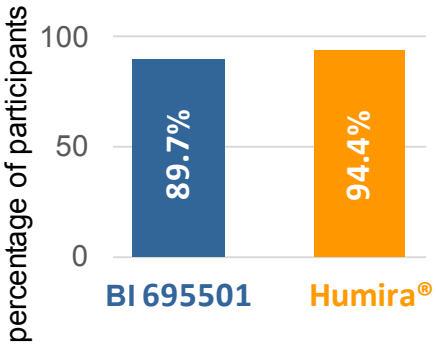
To compare BI 695501 with Humira®, we used a scale called the Crohn's Disease Activity Index (CDAI). The CDAI is based on symptoms of Crohn's disease and how they affect each participant's lifestyle. We wanted to know who had improved CDAI scores after 4 weeks of treatment with BI 695501 or Humira®.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health.

What were the results of this study?

We found that the percentage of participants who had improved CDAI scores after 4 weeks of treatment with BI 695501 or Humira® was similar. This means that BI 695501 and Humira® worked equally as well in participants with Crohn's disease. The percentages were also the same in both groups after 22 weeks of treatment.

Participants with an improved CDAI score



In both treatment groups, the percentage of participants with an improved CDAI score ≥70 was similar after 4 weeks.

Did participants have any unwanted effects?

Yes, participants in both treatment groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by BI 695501 or Humira®. During the first 24 weeks (Period 1), 15 out of 72 participants (21%) in the BI 695501 group had unwanted effects. 17 out of 75 participants (23%) in the Humira® group had unwanted effects.

The table below shows the most common unwanted effects during the first 24 weeks. The table also shows how many participants had each of these unwanted effects.

Type of unwanted effect	**BI 695501 72 participants were in this group**	**Humira® 75 participants were in this group**
Weight increased	3 participants (4%)	1 participant (1%)
High level of cholesterol (hypercholesterolaemia)	2 participants (3%)	0 participants
Hair loss (alopecia)	2 participants (3%)	0 participants
Painful joints (arthralgia)	2 participants (3%)	0 participants
Upper respiratory tract infection	0 participants	3 participants (4%)
Skin reddening at the injection site (injection site erythema)	0 participants	3 participants (4%)
Itchy skin (pruritus)	0 participants	2 participants (3%)

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital. Unwanted effects were also serious if the doctor thought they were serious for any other reason. During Period 1, 1 participant (1%) in the BI 695501 group had serious unwanted effects. 0 participants in the Humira® group had serious unwanted effects.

During Period 2, 10 out of 72 participants (14%) in the BI 695501 group had unwanted effects. 11 out of 75 participants (15%) in the Humira® group had unwanted effects.

The table below shows the most common unwanted effects during Period 2 when all participants took BI 695501. The table also shows how many participants had each of these unwanted effects.

Type of unwanted effect	**BI 695501 during Period 1/BI 695501 during Period 2** **72 participants were in this group**	**Humira® during Period 1/BI 695501 during Period 2** **75 participants were in this group**
Weight increased	2 participants (3%)	0 participants
Liver enzyme level increased (gamma glutamyl transferase increased)	2 participants (3%)	0 participants

During Period 2, no participants taking BI 695501 throughout the entire study had serious unwanted effects. 3 participants (4%) taking Humira® in Period 1 and then BI 695501 in Period 2 had serious 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 1297.4.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2016-000612-14.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02871635.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'BI 695501 versus Humira® in patients with active Crohn's disease: a randomized, double-blind, multicenter, parallel group, exploratory trial comparing efficacy, endoscopic improvement, safety, and immunogenicity'.

This was a Phase 3 study. This study started in January 2017 and finished in May 2019.

Are there additional studies?

If we do more clinical studies with BI 695501, you will find them on the websites listed above. To search for these studies, use the word BI 695501.

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.