BI 695501 compared with Humira® in patients with moderate to severe plaque psoriasis

This is a summary of a clinical study in plaque psoriasis. 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 695501 and the treatment of plaque psoriasis.

What was this study about?

Researchers compared 2 different treatments for plaque psoriasis. They wanted to find out whether a new medicine called BI 695501 is as effective as a medicine called Humira®.

This study started in September 2016 and finished in January 2018.

Why was the study needed?

This study was needed to confirm how well BI 695501 works compared with Humira® in patients with plaque psoriasis. BI 695501 is a new medicine approved to treat patients with certain diseases including rheumatoid arthritis and plaque psoriasis. It has been developed to be similar to Humira®. Past studies comparing BI 695501 with Humira® included only patients with rheumatoid arthritis.

Which medicines were studied?

Some patients received Humira® (adalimumab), and other patients received BI 695501. Each medicine is injected under the skin. They bind to a substance in the body called TNFα. Humira® and BI 695501 reduce the symptoms of plaque psoriasis by blocking the effects of TNFα.

Who participated in the study?

Patients with moderate to severe plaque psoriasis during the past 6 months or longer could enter this study.

A total of 317 patients were treated with BI 695501 or Humira® in the study. 159 patients received BI 695501 and 158 patients received Humira®. The patients were mostly men (64%). The average age was 43 years. The youngest patient was 18 years old. The oldest patient was 78 years old.

The table below shows the number of patients in different countries who took part in the study.

	Number of Patients BI 695501	Number of Patients Humira®
Poland	35	31
Ukraine	32	34
United States	28	38
Russian Federation	28	27
Germany	18	8
Czech Republic	12	15
Slovakia	5	5
Estonia	1	0

How was this study done?

Patients were divided into 2 groups of similar size to receive either BI 695501 or Humira®. Every patient had an equal chance of being in either group. The patients did not know which treatment they were given. The doctors did not know either.

Patients were given 80 mg of either BI 695501 or Humira® during the first visit. Then they received 40 mg of that same treatment one week later. After that, they received 40 mg of that same treatment every 2 weeks.

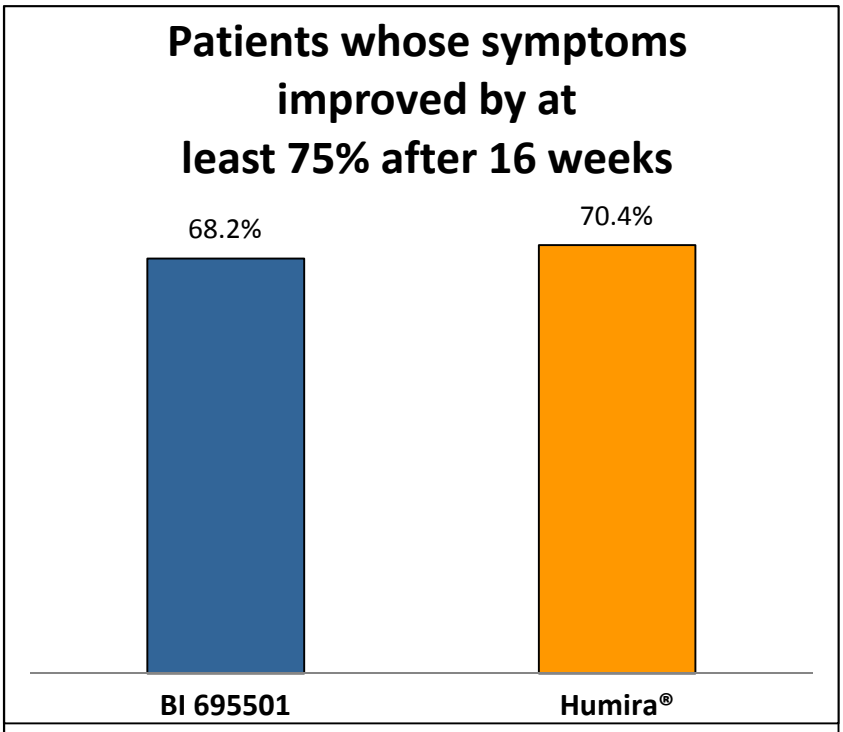
Patients visited their doctors regularly. During the visits, the doctors collected information on each patient's health.

Researchers wanted to know if the percentage of patients who improved after BI 695501 treatment was the same as after Humira® treatment. The doctors used a measurement called the Psoriasis Area and Severity Index (PASI). For this measurement, the doctors looked at the size and overall condition of each patient's skin plaques after 16 weeks. Patients with at least a 50% improvement in the PASI after 16 weeks could continue treatment for another 8 weeks.

What were the results of this study?

Researchers found that BI 695501 and Humira® were similar. After 16 weeks, more than 2 out of 3 patients who received BI 695501 or Humira® had at least a 75% improvement in their PASI score. The researchers compared the percentage of those patients who improved by at least 75%. They did statistical tests on the results. They found that BI 695501 was not different from Humira®.

The picture below shows the percentage of patients whose symptoms improved by at least 75% after 16 weeks of treatment.



Researchers found that BI 695501 and Humira® were similar. Nearly the same percentage of patients in each treatment group had an improvement in their symptoms by at least 75% according to the PASI after 16 weeks of treatment.

Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study, 21 out of 159 patients (13%) in the BI 695501 group had unwanted effects. 32 out of 158 patients (20%) in the Humira® group had unwanted effects.

The most common unwanted effects seen in at least 2% of patients in either group are shown in the table below.

	BI 695501 (159 patients)	**Humira® (158 patients)**
Redness at the injection site (injection site erythema)	4 patients (3%)	9 patients (6%)
Swelling at the injection site	3 patients (2%)	5 patients (3%)
Pain at the injection site	2 patients (1%)	8 patients (5%)
Bruising at the injection site	2 patients (1%)	4 patients (3%)
Itching at the injection site (injection site pruritus)	1 patient (1%)	5 patients (3%)
Hardened skin at the injection site (injection site induration)	1 patient (1%)	4 patients (3%)

Some unwanted effects were serious because they required a visit to a hospital. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, 1 patient (1%) in the BI 695501 group had serious unwanted effects. 2 patients (1%) in the Humira® group had serious unwanted effects.

Are there follow-up studies?

No follow-up study is planned.

If more clinical studies with BI 695501 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 695501 and adalimumab-adbm.

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: 1297.12
www.clinicaltrialsregister.eu/ctr-search	search for the EudraCT number: 2016-000613-79
www.clinicaltrials.gov	search for the NCT number: NCT02850965

The sponsor of this study was Boehringer Ingelheim.

The full title of the study is:

'Efficacy, Safety, and Immunogenicity of BI 695501 versus Humira® in Patients with Moderate to Severe Chronic Plaque Psoriasis: A Randomized, Double-Blind, Parallel-Arm, Multiple-Dose, Active Comparator Trial'.

This was a Phase III 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.