A study on the long-term safety of BI 695501 in patients with rheumatoid arthritis

This is a summary of a clinical study in rheumatoid arthritis. 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 rheumatoid arthritis.

What was this study about?

In this study, researchers wanted to look at the long-term safety of treatment with a medicine called BI 695501 in patients with rheumatoid arthritis.

This study started in January 2016 and finished in November 2017.

Why was the study needed?

Rheumatoid arthritis can cause a person's joints to become swollen, red, and painful. If it is not treated, severe rheumatoid arthritis can cause permanent joint damage. It can also cause problems in other parts of the body such as the lungs and eyes. Humira® is a medicine that is used to treat rheumatoid arthritis. The new medicine, BI 695501, has been designed to be similar to Humira®.

This study allowed patients from a previous study on BI 695501 to continue treatment with BI 695501 for a longer period of time. Researchers could then look at the long-term safety of BI 695501 in patients with rheumatoid arthritis.

Which medicines were studied?

BI 695501 is a medicine that reduces the symptoms of rheumatoid arthritis. It is given by an injection under the skin. BI 695501 was designed to be similar to another medicine called Humira®.

Who participated in the study?

Patients could take part in the study if they had rheumatoid arthritis and had completed a previous study on BI 695501.

A total of 430 patients were treated with BI 695501 in the study. There were 360 women and 70 men. The average age was 54 years. The youngest patient was 22 years old. The oldest patient was 80 years old. The table below lists the regions and countries where patients took part in the study.

Region	Countries	Number of patients
Europe	Bulgaria, Estonia, Germany, Hungary, Poland, Russia, Serbia, Spain, Ukraine	342 patients
North America	United States	57 patients
South America	Chile	24 patients
Asia	South Korea, Malaysia, Thailand	7 patients

How was this study done?

In this study, patients injected themselves with 40 mg BI 695501 every 2 weeks. The treatment with BI 695501 continued for up to 48 weeks. The patients and their doctors knew that the study treatment was BI 695501.

During the study, patients visited their doctors regularly. During these visits, the doctors collected information about any health problems the patients had. Researchers were most interested in health problems that the doctors thought were caused by BI 695501.

What were the results of this study?

Unwanted effects are any health problems that the doctors thought were caused by the study medicine. In this study, 87 out of 430 patients (20%) had unwanted effects. The unwanted effects seen in at least 5 patients are shown in the table below.

	BI 695501 (430 patients)
Bruising at the injection site	12 patients (3%)
Redness (erythema) at the injection site	10 patients (2%)
Runny nose or common cold (nasopharyngitis)	6 patients (1%)
Sore throat (pharyngitis)	6 patients (1%)
Bronchitis	6 patients (1%)
Increased liver enzymes (aspartate aminotransferase)	5 patients (1%)

Some unwanted effects were serious because they required a longer stay in hospital or because the doctor thought they were serious for any other reason. For 9 of the patients (2%), the unwanted effects they had were serious.

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 name: BI 695501.

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: 1297.3
www.clinicaltrialsregister.eu/ctr-search	search for the EudraCT number: 2015-002634-41
www.clinicaltrials.gov	search for the NCT number: NCT02640612

The sponsor of this study was Boehringer Ingelheim.

The full title of the study is:

Long-term assessment of safety, efficacy, pharmacokinetics and immunogenicity of BI 695501 in patients with rheumatoid arthritis (RA): an open-label extension trial for patients who have completed Trial 1297.2 and are eligible for long-term treatment with adalimumab

This was a Phase 3b 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.