

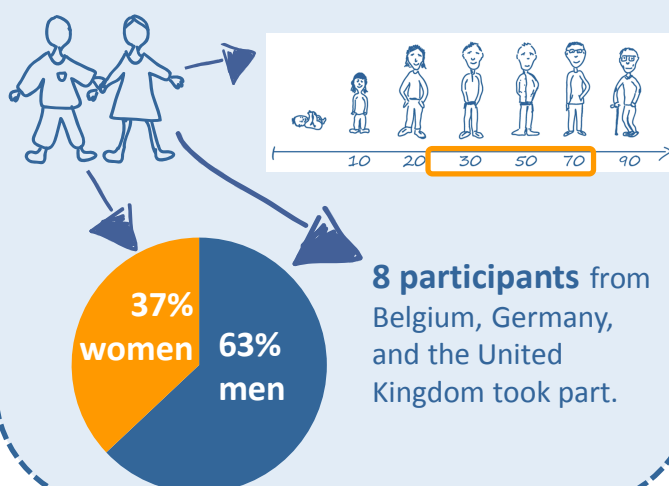
A study to test how spesolimab works in people with active ulcerative colitis

Ulcerative colitis is an inflammation of the gut.

This **study** was to find out:

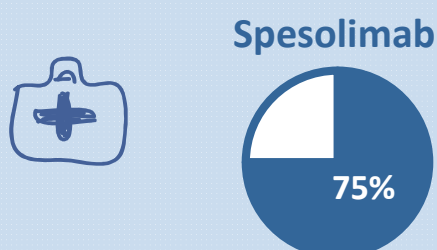
➔ Does a biologic medicine called **spesolimab** (BI 655130) have an effect on the activity of certain **genes** associated with **ulcerative colitis**?

Participants who took part had moderate to severe active ulcerative colitis. They had not previously taken any biologic medicines.



Each participant received an intravenous infusion of **spesolimab** at the **start** of the study as well as after **1 and 2 months**.

6 out of 8 participants (75%) who took spesolimab had **unwanted effects**. None of the unwanted effects were serious.



RESULTS

Overall, spesolimab did not have a consistent effect on the gene activity associated with ulcerative colitis in patients who had not previously received biologic treatments.

A study to test how spesolimab works in people with active ulcerative colitis.

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about spesolimab and the treatment of ulcerative colitis.



What was this study about?

The purpose of this study was to find out how a medicine called spesolimab (BI 655130) works in ulcerative colitis.

Ulcerative colitis causes inflammation of the part of the gastrointestinal tract called the large intestine (colon). This can lead to abdominal pain, diarrhoea, fever, and sores and scarring in the colon. Ulcerative colitis can be painful and debilitating. For people with ulcerative colitis, the current medicines may help or may not. New medicines are needed to give people more options for treatment.

Spesolimab is a medicine that was developed to reduce inflammation. Spesolimab is a type of medication called a biologic. It blocks a receptor in the body called interleukin-36 receptor (IL-36R) which may cause inflammation. Spesolimab is given by an infusion into a vein. The study wanted to test whether spesolimab had an effect on the activity of the genes that are associated with ulcerative colitis. Learning more about inflammation and the genes associated with ulcerative colitis may help people with ulcerative colitis.



Who took part in this study?

People with moderate to severe active ulcerative colitis for at least 3 months and who were 18 years of age and older could take part in the study. They could not have previously taken a biologic medicine. They had to be taking other medicines for ulcerative colitis for 3 months before starting the study.

Overall, 8 participants took part in the study. 5 were men (63%) and 3 were women (37%). The average age was 43 years. The youngest participant was 23 years old and the oldest participant was 76 years old.

All study participants were from Belgium, Germany, and the United Kingdom.



How was this study done?

All participants received an infusion into a vein of spesolimab at the start of the study. After 1 month, and again after 2 months, they received another infusion of spesolimab. Participants continued to receive the medications they were taking for their ulcerative colitis. Participants were followed for a total of 7 months.

We looked at the effect of spesolimab on the activity of the genes associated with ulcerative colitis. To do this, we collected colon biopsies from participants before and after treatment with spesolimab.

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



What were the results of this study?

Overall, spesolimab did not have a consistent effect on the gene activity associated with ulcerative colitis in patients who had not previously received biologic treatments.



Did participants have any unwanted effects?

Yes, participants had unwanted effects. Unwanted effects are health problems that the doctors think were caused by spesolimab. In this study, 6 out of 8 participants (75%) had unwanted effects. Some of the unwanted effects were: common cold (nasopharyngitis), headache, bleeding in the eye (conjunctival haemorrhage), raised red rash (dermatitis acneiform), small red rash (rash macular), joint pain (arthralgia), body pain (musculoskeletal pain), muscle pain (myalgia), pain in extremity, fatigue, and increased levels of enzymes produced by the liver and pancreas (amylase and lipase increased).

None of the unwanted effects were serious. This means that the unwanted effects did not lead to a hospital stay, that they were not life-threatening, and that they did not lead to a disability.



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 1368-0004.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2017-000100-20.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03100864.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'Exploratory trial to assess mechanism of action, clinical effect, safety and tolerability of 12 weeks of treatment with BI 655130 in patients with active ulcerative colitis (UC)'.

This was a Phase 2 study. This study started in May 2017 and finished in October 2019.



Are there additional studies?

If we do more clinical studies with spesolimab, you will find them on the websites listed above. To search for these studies, use the words spesolimab and BI 655130.

People with ulcerative colitis who took part in this study with spesolimab were also able to take part in an additional study with spesolimab.

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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