

A study in patients with mild or moderate ulcerative colitis who take a TNF inhibitor. The study investigates whether bowel inflammation improves when patients take BI 655130 (spesolimab) in addition to their current therapy.

**Ulcerative colitis** causes inflammation of the part of the gastrointestinal tract called the large intestine (colon). It can be painful and debilitating.

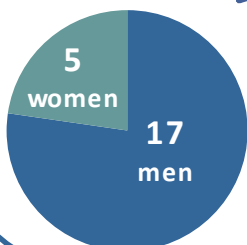
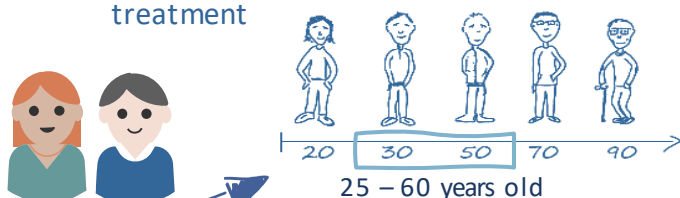
This **STUDY** was done to find out:

→ Does a medicine called **spesolimab** together with a **TNF inhibitor** help people with **ulcerative colitis** more than taking **TNF inhibitor** by itself?



## Participants...

- ✓ had ulcerative colitis for at least 5 months and have already received TNF inhibitor treatment



There were **22 participants** from **Europe and United Kingdom**.

Once every month, participants received as an infusion into a vein:



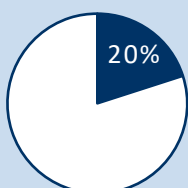
3 doses in total of **spesolimab** or placebo, which didn't contain any medicine

Participants in both groups also continued to take their TNF inhibitor therapy.

**20%** of the spesolimab group and **14%** of the placebo group had **unwanted effects**.

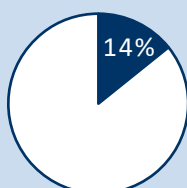


### Spesolimab



**3 out of 15 participants**

### Placebo



**1 out of 7 participants**

## RESULTS

2 participants in the spesolimab group and 3 participants in the placebo group had **improved healing** inside the colon. The study was stopped early. There were not enough participants to reach clear conclusions about the results of the study.

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A study in patients with mild or moderate ulcerative colitis who take a TNF inhibitor. The study investigates whether bowel inflammation improves when patients take BI 655130 in addition to their current therapy.

This is a summary of results from 1 clinical study.

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We thank all study participants. You helped us to answer important questions about spesolimab (BI 655130) and the treatment of ulcerative colitis.

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### What was this study about?

The purpose of this study was to find out whether taking a medicine called spesolimab with an approved medicine called a TNF inhibitor helps people with ulcerative colitis more than taking the TNF inhibitor by itself.

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. TNF inhibitors are 1 type of medicine used to treat ulcerative colitis. For people with ulcerative colitis, the current medicines may help or may not. Adding another medicine like spesolimab could provide added benefit and more options for treatment.

The study was stopped early. This was because we could not find enough people who wanted to participate.



### Who took part in this study?

Adults who had ulcerative colitis for at least 5 months could take part in this study. This study was for people who were already receiving a TNF inhibitor for treatment.

30 participants were planned to take part in the study. This study was stopped early because fewer patients took part in the study than were planned. 22 participants took part in the study. 17 were men and 5 were women. The youngest participant was 25 years old and the oldest participant was 60 years old. The average age was 44 years.

The 22 participants were in Germany, United Kingdom, Netherlands, Denmark, Norway, and Spain.



## How was this study done?

At the start of the study, participants were divided into 2 groups. The groups were:

- Spesolimab group: participants received spesolimab as an infusion into a vein once every month for a total of 3 doses. Participants also continued to take their TNF inhibitor therapy.
- Placebo group: participants received placebo as an infusion into a vein once every month for a total of 3 doses. Participants also continued to take their TNF inhibitor therapy.

Placebo infusions looked like spesolimab infusions but did not contain any medicine. Every participant had a 2 in 3 chance of receiving spesolimab. The participants and doctors did not know whether the participants were in the spesolimab group or in the placebo group.

To find out if adding spesolimab to TNF inhibitor therapy helps people with ulcerative colitis, we looked at the number of participants who had improved healing of sores inside their colon after 12 weeks. We compared the results from the 2 groups.

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



## What were the results of this study?

2 out of 14 participants in the spesolimab group and 3 out of 8 participants in the placebo group had improved healing inside the colon. The study was stopped early. There were not enough participants to reach clear conclusions about the results of the study.



## Did participants have any unwanted effects?

Yes, participants in the spesolimab and the placebo groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by spesolimab or placebo. In this study, 3 out of 15 participants (20%) in the spesolimab group had unwanted effects. 1 out of 7 participants (14%) in the placebo group had unwanted effects. The unwanted effects were infected sore of the rectum (rectal abscess), ulcerative colitis, nausea, acne, pain in the joints (arthralgia), and flu-like illness.

Some unwanted effects were serious because they required a stay in hospital or a longer stay in hospital. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, none of the participants in the spesolimab group had serious unwanted effects. 1 participant (14%) in the placebo group had serious unwanted effects of a pus-filled swelling (rectal abscess) and severe ulcerative colitis.



## 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.mystudywindow.com> and search for the study number 1368-0010.
2. Go to [www.clinicaltrialsregister.eu/ctr-search](http://www.clinicaltrialsregister.eu/ctr-search) and search for the EudraCT number 2016-004572-21.
3. Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search for the NCT number NCT03123120.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'Proof-of-concept study of BI 655130 add-on treatment in patients with mild-to-moderately active ulcerative colitis during TNF inhibitor therapy'.

This was a Phase 2 study. This study started in July 2017 and finished in September 2020.



## 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 terms spesolimab or BI 655130.

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## Important notice

This lay summary is provided as part of Boehringer Ingelheim's commitment to publicly share clinical study results.

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Other studies may have different results. Usually, more than one study is carried out to find out how well a medicine works and to determine the side effects of a medicine.

This lay summary may include uses, formulations, or treatment regimens for the medicine studied that may be approved or not approved in your country. This lay summary is not intended to promote any product or indication, to guide treatment decisions, or to replace the advice of a healthcare professional.

You should not change your therapy based on the results of this study. Always consult with your treating physician about your therapy.

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