

A study to test spesolimab in patients with ulcerative colitis

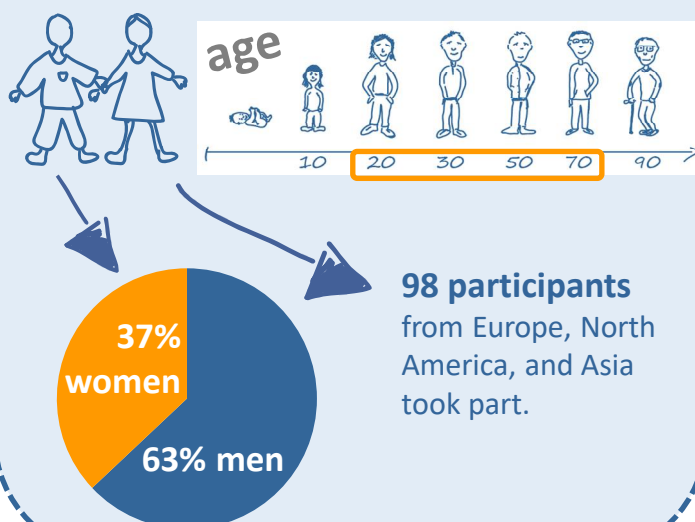
Ulcerative colitis is a condition that causes inflammation of the gut.

This **study** was to find out:



Does a medicine called **spesolimab** (BI 655130) help to **improve** the symptoms of **ulcerative colitis**?

Participants had moderate to severe active ulcerative colitis and their previous treatment was not successful.



Participants received different doses of spesolimab or placebo as infusions into a vein.

There were 4 groups of participants.

Group 1: 1 infusion of placebo every 4 weeks for 12 weeks

Group 2: single infusion of a low dose of spesolimab, then infusions of placebo every 4 weeks for 12 weeks

Group 3: 1 infusion of a medium dose of spesolimab every 4 weeks for 12 weeks

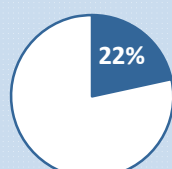
Group 4: 1 infusion of a high dose of spesolimab every 4 weeks for 12 weeks



Participants in all groups had **unwanted effects**.

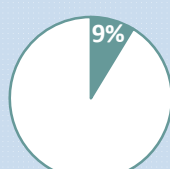


Spesolimab combined groups



16 out of 74 participants

Placebo



2 out of 23 participants

Rash was the most common unwanted effect. 5% of participants who received spesolimab had this unwanted effect.

RESULTS

The study was **stopped early** because there were **not enough** participants.

The number of participants who had little or no symptoms of ulcerative colitis after treatment **did not differ** between the 4 treatment groups.

A study to test spesolimab in patients with ulcerative colitis

This is a summary of results from 1 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 whether a medicine called spesolimab helps to improve the symptoms of 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 affect daily activities. 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. In this study we tested whether spesolimab improves the symptoms of ulcerative colitis.

The study was stopped early because it was harder than expected to find participants. The study was planned to have 2 parts. It was stopped after the first part, because there were not enough participants.



Who took part in this study?

People could take part in this study if they were aged between 18 and 75 years and had moderate to severe active ulcerative colitis for at least 3 months. People for whom previous treatment with medicines called TNF- α antagonists and/or vedolizumab was not successful could join this study.

Overall, 98 participants took part in the study. The study included 62 men (63%) and 36 women (37%). The average age was 43 years. The youngest participant was 19 years old and the oldest participant was 73 years old.

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

Region	Countries	Number of Participants
Europe	Austria, Belgium, Germany, Italy, Poland, Spain, United Kingdom	56
North America	Canada, United States	22
Asia	Japan, Republic of Korea, Russian Federation	20



How was this study done?

The participants were divided into 4 groups of almost equal size. The groups were:

- Group 1: participants received 1 infusion of placebo into a vein every 4 weeks for 12 weeks
- Group 2: participants received a single infusion of a low dose of spesolimab into a vein, then infusions of placebo every 4 weeks for 12 weeks
- Group 3: participants received 1 infusion of a medium dose of spesolimab into a vein every 4 weeks for 12 weeks
- Group 4: participants received 1 infusion of a high dose of spesolimab into a vein every 4 weeks for 12 weeks

Placebo infusions looked like spesolimab but did not contain any medicine. We compared spesolimab with placebo to find out how well spesolimab works.

Participants and doctors did not know in which group the participants were.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health. Doctors looked at improvements in ulcerative colitis symptoms. We wanted to know how many participants had little or no symptoms of ulcerative colitis after 12 weeks of treatment.



What were the results of this study?











The study was stopped early because there were not enough participants. In this study, the number of participants who had little or no symptoms of ulcerative colitis after 12 weeks of treatment was not any different between the 4 treatment groups.



Did participants have any unwanted effects?

Yes, participants in all groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by spesolimab or placebo. In this study, 16 out of 74 participants (22%) in the spesolimab groups had unwanted effects. 2 out of 23 participants (9%) in the placebo group had unwanted effects.

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

Type of unwanted effect	Spesolimab 74 participants 	Placebo 23 participants 
Rash	4 participants (5%) 	0 participants 
Common cold (nasopharyngitis)	3 participants (4%) 	0 participants 
Headache	2 participants (3%) 	0 participants 
Reaction caused by the infusion	2 participants (3%) 	1 participant (4%) 

Some unwanted effects were serious because they were life-threatening or the doctor thought they were serious for any other reason. In this study, 1 participant (1%) in the spesolimab group had serious unwanted effects. 1 participant (4%) in the placebo group had serious unwanted effects. For both of these participants the serious unwanted effect was a reaction caused by the infusion.



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 1368-0005.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2017-004230-28.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03482635.

Boehringer Ingelheim sponsored this study.

The full title of the study is:

A Phase II/III Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Safety and Efficacy of BI 655130 (SPESOLIMAB) Induction Therapy in patients with moderate-to-severely active ulcerative colitis who have failed previous biologics therapy

This trial was prematurely discontinued.

This study started in July 2018 and finished in May 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 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 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.

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