



## Clinical Trial Results – Layperson Summary

### A study to compare the safety and effectiveness of etrolizumab with placebo in people with “ulcerative colitis,” a long-term illness where the lower part of the gut is inflamed

See the end of the summary for the full title of the study.

#### About this summary

This is a summary of the results of a clinical trial (called a “study” in this document), written for:

- Members of the public, and
- People who took part in the study.

This summary is based on information known at the time of writing (November 2021). More information may now be known.

The study started in August 2014 and finished in June 2020. This summary was written after the study had ended.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

- This means that you should not make decisions based on this one summary—always speak to your doctor before making any decisions about your treatment.

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#### Thank you to the people who took part in this study

The people who took part have helped researchers to answer important questions about the study medicine, and a long-term illness called “ulcerative colitis,” an inflammatory bowel disease where the lower part of the gut is inflamed.

## Key information about this study

Key methods	Key findings
<ul style="list-style-type: none"><li>● This study was done to compare the study medicine, called “etrolizumab,” with a placebo, which looked the same as the study medicine but did not contain any real medicine, in people with ulcerative colitis. The study also looked at how safe etrolizumab was.</li><li>● In this study, people received either etrolizumab or placebo. It was decided by chance using a computer which treatment each person received.</li><li>● This study included 359 people in 24 countries.</li></ul>	<ul style="list-style-type: none"><li>● The main finding of this study was that after 1 year of receiving treatment, the number of people with ulcerative colitis who had reduced inflammation and symptoms was overall similar between people who received etrolizumab (30 out of 100) and people who received placebo (21 out of 100).</li><li>● One person who received etrolizumab in both parts of the study had a serious side effect (a rectal abscess) that the study doctor believed was related to receiving etrolizumab or placebo study medicine.</li><li>● At the time of writing this summary, the study has concluded. No new information is being collected.</li></ul>

## 1. General information about this study

### Why was this study done?

Ulcerative colitis is a long-term illness where the lower part of the gut becomes inflamed, causing ulcers to form. People with ulcerative colitis often experience diarrhea with blood, stomach cramps, and the urgent need to have a bowel movement. These painful and debilitating symptoms can get in the way of sleep, social activities, and other daily activities.

There are different types of medicines available to help treat ulcerative colitis and its symptoms. These medicines often do not work for everyone, or don't work for a long time in some people with ulcerative colitis, so researchers are looking at new medicines that work in other ways.

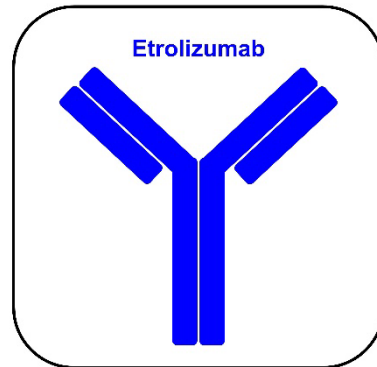
This study looked at etrolizumab, which works differently in the body than existing medicines. The study doctors wanted to find out if etrolizumab could reduce the symptoms of ulcerative colitis. They also wanted to find out how safe etrolizumab was.

## What was the study medicine?

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A medicine called “etrolizumab” was the focus of this study.

- You say this as “et – roe – liz – oo – mab.”
- Etrolizumab is a type of protein called an “antibody.” It works by sticking to and blocking a second protein, called “ $\beta$ 7.” You say this as “bay-tuh seh-ven.”
  - This prevents the movement of inflammatory cells into the gut and decreases inflammatory processes in the gut.
- Etrolizumab is given as an injection under the skin.



Etrolizumab was compared with a “placebo.”

- You say this as “plah – see – bo.”
- The placebo looked the same as etrolizumab but did not contain any real medicine. This means it had no medicine-related effect on the body.
- Researchers compared etrolizumab with a placebo so they could show which benefits or side effects are actually caused by the medicine.

## What did researchers want to find out?

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Researchers did this study to find out how well etrolizumab worked compared with a placebo (see section 4, “What were the results of the study?”).

They also wanted to find out how safe etrolizumab was, by checking how many people had side effects when taking each of the medicines during this study (see section 5, “What were the side effects?”).

**The main questions that researchers wanted to answer were:**

1. Among the people who had their ulcerative colitis inflammation and symptoms reduced at week 10, how many still had reduced inflammation and symptoms after 1 more year of treatment?
2. Did people who received etrolizumab have any side effects, and if so, what were they?

## What kind of study was this?

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This study was a “phase 3” study. This means that etrolizumab’s efficacy and safety had been tested in a smaller number of people with ulcerative colitis before this study (called a “phase 2” study). In this phase 3 study, a larger number of people with ulcerative colitis either received etrolizumab or a placebo. This was to find out about the side effects of etrolizumab and to see if etrolizumab reduced inflammation and symptoms.

The study was “randomized.” This means that it was decided by chance, like tossing a coin, whether people in the study would receive etrolizumab or placebo. This was done by a computer.

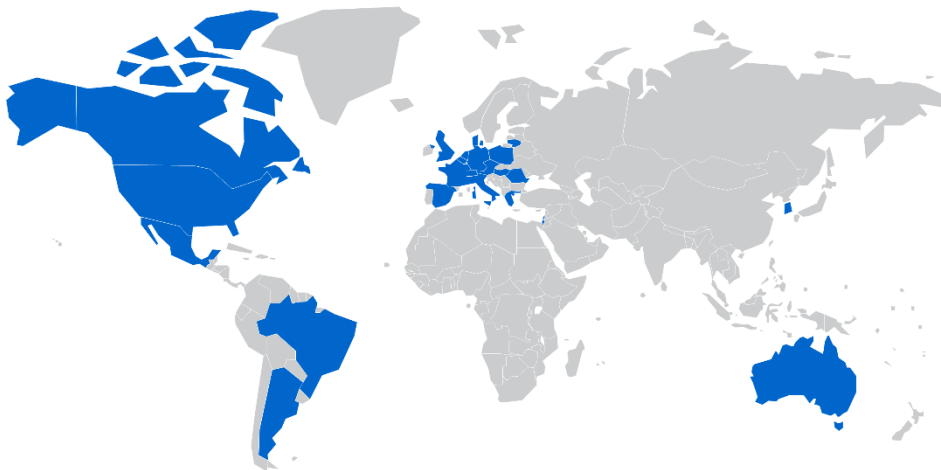
**Part 1** of the study was a 10-week “open-label” study. This means that both the people taking part in the study, and the study doctors, knew which of the treatments people were receiving. This part of the study aimed to find out if etrolizumab reduced inflammation and symptoms in people with ulcerative colitis. People could continue into **Part 2** of the study if etrolizumab reduced their inflammation and symptoms.

**Part 2** of the study was a 52-week “double-blind” study. This means that neither the people taking part in the study, nor the study doctors, knew which of the treatments people were receiving. “Blinding” of a study is done so that the person does not know which treatment they are receiving and what effect of the treatment to expect. This part of the study was to find out if people still had reduced inflammation and symptoms after a further year of treatment.

### When and where did the study take place?

The study started in August 2014 and finished in June 2020. This summary was written after the study had ended.

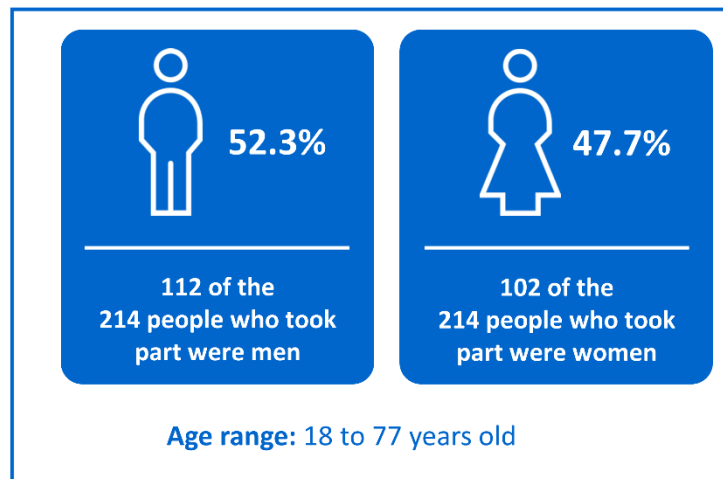
The study took place at 111 study centers, across 24 countries in Asia-Pacific, Europe, North America, and South America. The following map shows the countries where this study took place.



- Argentina
- Australia
- Austria
- Belgium
- Brazil
- Canada
- Czech Republic
- Denmark
- France
- Germany
- Greece
- Hungary
- Israel
- Italy
- (Republic of) Korea
- Lithuania
- Mexico
- Netherlands
- Poland
- Romania
- Spain
- Switzerland
- United Kingdom
- United States

## 2. Who took part in this study?

In this study, 359 people with ulcerative colitis participated in **Part 1** and 214 people continued into **Part 2**. More information on the people who were in **Part 2** of the study is given below.



People **could** take part in the study if they:

- Were aged 18 to 80 years
- Had been diagnosed with ulcerative colitis more than 3 months before starting the study
- Had never received tumor necrosis factor (or called “TNF” for short) inhibitors (such as infliximab).

People **could not** take part in the study if they had:

- A history of certain stomach and gut problems, such as a past or present abnormal connection between parts of the gut (called a “fistula”) or a painful collection of pus (called an “abscess”) in their abdomen, colon polyps that appear to be cancerous (colonic mucosal dysplasia), or a narrowed large intestine, or infections such as HIV or hepatitis B or C, or tuberculosis (to avoid potential safety issues)
- Previously taken certain medicines, such as corticosteroid enemas or suppositories, 5-aminosalicylate preparations rectally, or anti-TNF therapy (including infliximab), or anti-integrin therapy (including vedolizumab or natalizumab)
- Surgery to treat their ulcerative colitis or other stomach or gut problems, including surgery to remove part of the colon to remove cancer (colonic resection or colectomy), or surgery to divert part of the intestine through the abdomen wall (ileostomy or colostomy).

### 3. What happened during the study?

There were two parts to this study. In **Part 1**, all people received etrolizumab. In **Part 2**, people were selected by chance to receive one of two treatments: etrolizumab or placebo. The treatments given in **Part 2** were selected at random by a computer. People received the treatments at the study center.

#### **Part 1: this lasted about 2.5 months (10 weeks)**

The treatment group was:

- **Etrolizumab (the study medicine) group:** 105 milligrams injected under the skin every 4 weeks.
  - Everyone (359 people) received etrolizumab.

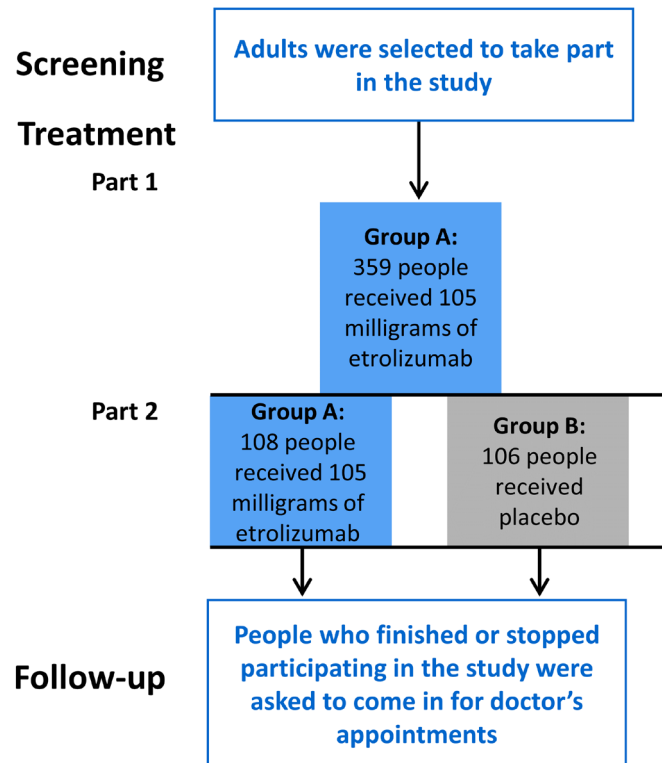
#### **Part 2: this lasted about 12 months (52 weeks)**

Only people who had reduced inflammation and symptoms by the end of **Part 1** (214 people) stayed in the study for **Part 2**.

The treatment groups were:

- **Etrolizumab (study medicine) group:** 105 milligrams injected under the skin every 4 weeks.
  - 108 people were randomly assigned to this group.
- **Placebo group:** injected under the skin every 4 weeks.
  - 106 people were randomly assigned to this group.

People in the study attended the study center to receive their treatments for up to 62 weeks. When the study finished, the people who took part were asked to go back to their study center for transfer to another study, called an open-label study, where they continued to receive etrolizumab or had follow-up visits to check their overall health. Look below to see more information about what happened in the study.



#### 4. What were the results of the study?

**Among the people who had their ulcerative colitis inflammation and symptoms reduced at week 10, how many still had reduced inflammation and symptoms after 1 more year of treatment?**

Researchers looked at the number of people with reduced ulcerative colitis inflammation and symptoms at the end of week 10 who also had reduced symptoms after 1 more year of treatment.

About 30 out of 100 people (30%) who received etrolizumab had reduced ulcerative colitis inflammation and symptoms of ulcerative colitis, compared with about 21 out of 100 people (21%) taking the placebo after 1 year of treatment.

**Overall, after 1 year, a similar number of people who received etrolizumab had reduced symptoms as those who received placebo.**

## 5. What were the side effects?

Side effects (also known as “adverse reactions”) are unwanted medical problems (such as a headache) that happen during a study.

- Only side effects that the study doctor believed were related to the study treatments are described below.

Serious and common side effects are listed in the following sections. Because LAUREL looked at how many people continued to have reduced inflammation and symptoms after 1 year of receiving treatment, only side effects that occurred in people who were in Part 2 of the study are included below.

### **Serious side effects that the study doctor believed were related to the treatment**

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A side effect is considered “serious” if it is life-threatening, needs hospital care, or causes lasting problems.

No person who received etrolizumab in both parts of the study had a serious side effect that the study doctor believed was related to the study medicine. During the study, one person who received etrolizumab in Part 1 and placebo in Part 2 had a serious side effect that was believed by the study doctor to be related to taking study medicine. This side effect was a rectal abscess.

During the study, there were no people who decided to stop taking their medicine due to related side effects.

### **Most common side effects that the study doctor believed were related to the treatment**

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Around 9 out of 100 people (9%) who received etrolizumab in both parts of the study had a side effect that was believed by the study doctor to be related to taking the study medicine, compared with around 15 out of 100 people (15%) who received etrolizumab in Part 1 and placebo in Part 2 of the study.

In people who received etrolizumab in both parts of the study, the most common side effects that the study doctor believed were related to the treatment was acne. The most common side effects for people who received etrolizumab in Part 1 and placebo in Part 2 were redness at the injection site, fatigue, pain, and oral herpes.

### **Other side effects**

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You can find information about other side effects (not shown in the sections above, such as side effects that doctors did not consider to be related to etrolizumab) on the websites listed at the end of this summary (see section 8, “Where can I find more information?”).



## 6. How has this study helped research?

The information presented here is from a single two-part study of 359 people with ulcerative colitis. These results helped researchers learn more about ulcerative colitis and etrolizumab.

No single study can tell us everything about the risks and benefits of a medicine. It takes lots of people in many studies to find out everything we need to know. The results from this study may be different from other studies with the same medicine.

This means that you should not make decisions based on this one summary—always speak to your doctor before making any decisions about your treatment.

## 7. Are there plans for other studies?

At the time of writing this summary (November 2021), this study has been completed and no more information is being collected. The main finding of this study was that after 1 year of receiving treatment, the number of people with ulcerative colitis who had reduced inflammation and symptoms of ulcerative colitis was overall similar between people who received etrolizumab (30 out of 100) and people who received placebo (21 out of 100). One person who received etrolizumab had a serious side effect (a rectal abscess) that the study doctor believed was related to receiving the study medicine.

Other phase 3 studies looking at the safety and effects of etrolizumab in people with ulcerative colitis who have not received TNF inhibitors (such as infliximab) have taken place.

Currently, researchers are studying etrolizumab in adults with Crohn's disease.

## 8. Where can I find more information?

You can find more information about this study on the websites listed below:

- <https://clinicaltrials.gov/ct2/show/study/NCT02165215>
- <https://www.clinicaltrialsregister.eu/ctr-search/trial/2013-004280-31/results>
- <https://forpatients.roche.com/en/trials/autoimmune-disorder/ulcerative-colitis/a-study-of-the-efficacy-and-safety-of-etrolizumab-treatment-in-m.html>.

### Who can I contact if I have questions about this study?

If you have any further questions after reading this summary:

- Visit the ForPatients platform and fill out the contact form:  
<https://forpatients.roche.com/en/trials/autoimmune-disorder/ulcerative-colitis/a-study-of-the-efficacy-and-safety-of-etrolizumab-treatment-in-m.html>
- Contact a representative at your local Roche office.

If you took part in this study and have any questions about the results:

- Speak with the study doctor or staff at the study hospital or clinic.

If you have questions about your own treatment:

- Speak to the doctor in charge of your treatment.

### **Who organized and paid for this study?**

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This study was organized and paid for by F. Hoffmann-La Roche Ltd., which has its headquarters in Basel, Switzerland.

### **Full title of the study and other identifying information**

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The full title of this study is: "Etrolizumab for maintenance therapy in patients with moderately-to-severely active ulcerative colitis."

The study is known as "LAUREL."

- The protocol number for this study is: GA29102.
- The ClinicalTrials.gov identifier for this study is: NCT02165215.
- The EudraCT number for this study is: 2013-004280-31.