

Ulcerative Colitis

A Clinical Trial to Compare Etrolizumab with Placebo and Adalimumab in Patients with Moderate to Severe Ulcerative Colitis Who Have not Received Treatment with Tumour Necrosis Factor Inhibitors (Hibiscus II)

A Study Comparing the Efficacy and Safety of Etrolizumab With Adalimumab and Placebo in Participants With Moderate to Severe Ulcerative Colitis (UC) in Participants Naive to Tumor Necrosis Factor (TNF) Inhibitors (Hibiscus II)

Trial Status
Active, not recruiting

Trial Runs In
19 Countries

Trial Identifier
NCT02171429 2013-004277-27
GA28949

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This Phase III, double-blind, placebo and active comparator controlled, multicenter study will investigate the efficacy and safety of etrolizumab in induction of remission in participants with moderately to severely active UC who are naive to TNF inhibitors and refractory to or intolerant of prior immunosuppressant and/or corticosteroid treatment.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

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Trial Identifiers

Eligibility Criteria:

Gender
All

Age
≥ 18 Years & ≤ 80 Years

Healthy Volunteers
No

How does the Hibiscus II clinical trial work? This clinical trial is recruiting people who have 'ulcerative colitis', a condition that results in inflammation and ulcers in the large intestine or bowel ('colon') or back passage ('rectum'). It is for people whose ulcerative colitis is categorised as moderately to severely active.

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How do I take part in this clinical trial? To be able to take part in this clinical trial, you must not have already been given a type of medicine called a 'tumour necrosis factor inhibitor' for your ulcerative colitis and you must have been diagnosed with ulcerative colitis at least 3 months before the start of this trial.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor.

If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor who will give you all the information you need to make your decision about taking part in the clinical trial. You will also find the clinical trial locations at the top of this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests and procedures may be part of your regular medical care and may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

This clinical trial is divided into three parts or 'phases'. These parts are called the:

- 'Screening phase' where the clinical trial doctor will check your suitability for the trial, this lasts for up to 5 weeks.
- 'Treatment phase' where you will be given the trial medicine, this lasts for up to 14 weeks. After the treatment phase, if you are eligible you may be asked if you would like to take part in an additional trial called the [COTTONWOOD](#) trial (also known as the 'Open Label Extension Trial') to receive the etrolizumab drug. If you do not qualify or choose not to join, then you would continue onto the next 'Safety Monitoring' phase.
- 'Safety monitoring follow-up phase' where the clinical trial doctor will check if you are having any side effects, this lasts for 12 weeks.

The maximum length of time you will be in this trial is 31 weeks.

What happens during the screening phase? During the screening phase, you will be told about any risks and benefits of taking part in the trial and what other treatments are available so that you may decide if you still want to take part. While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take effective contraceptive medications while taking part in the trial for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be split into three groups randomly (like flipping a coin) and given one of three different treatments in a blinded fashion.

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This is a 'placebo-controlled' clinical trial, which means that one of the groups will be given only injections with no active drug (also known as a placebo). At the start of the treatment phase, a computer will randomly choose your treatment group. This will be one of:

- Treatment with active etrolizumab (and an adalimumab placebo).
- Treatment with active adalimumab (and an etrolizumab placebo).
- Treatment with placebo only (an etrolizumab placebo and an adalimumab placebo).

You will have a 2 in 5 chance of being given etrolizumab and the placebo, a 2 in 5 chance of being given adalimumab and the placebo, and a 1 in 5 chance of being given only placebo treatment.

To allow a fair comparison between etrolizumab and adalimumab, you and your clinical trial doctor will be 'blinded' to treatment. This means that neither you nor your clinical trial doctor will know which treatments you are taking. If your safety is at risk, your clinical trial doctor can find out which drug you are being given.

How often will I be seen in follow-up appointments, and for how long? During the treatment phase, you will be asked to keep an electronic diary at home to record how you are feeling and managing with day-to-day activities. You will also come to the hospital every 2 weeks to be given your medicine. The clinical trial doctor will ask you about how your ulcerative colitis is responding to the treatment and about any side effects that you may be having.

At the Week 10 visit, you will be assessed by the clinical trial doctor to see if your ulcerative colitis has responded to treatment.

If, at Week 10 your ulcerative colitis has responded to treatment, you will continue for another 4 weeks and be given one more dose of etrolizumab or placebo at the Week 12 visit. No more doses of adalimumab will be given after Week 8. You will be assessed at Week 14 to see if you are still responding to treatment. After this assessment, you will either enter the safety monitoring follow-up phase of this clinical trial or your doctor will talk to you about entering the Open Label Extension Trial [COTTONWOOD](#) where you will be given long-term treatment with etrolizumab. The clinical trial doctor will give you all the information you need to make your decision about taking part in this other clinical trial.

If you have not met the required response at the Week 10 visit, you will either enter the 12-week safety monitoring follow-up phase, or if suitable, your doctor will talk to you about entering the Open Label Extension Trial [COTTONWOOD](#) where you will be given long-term treatment with etrolizumab. The clinical trial doctor will give you all the information you need to make your decision about taking part in this other clinical trial.

What happens during the safety monitoring follow-up phase? All patients who leave this trial and do not enter the other clinical trial of long-term treatment with etrolizumab will

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be asked to complete a 12#week safety monitoring follow-up phase. This will include one safety monitoring telephone call at Week 6 and one clinic visit at Week 12.

What happens if I'm unable to take part in this clinical trial? If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other treatments for you that you can be given or other clinical trials that you may be able to take part in. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on this page or follow this link to ClinicalTrials.gov <https://clinicaltrials.gov/ct2/show/NCT02171429>

Trial-identifier: NCT02171429