ForPatients
by Roche

Ulcerative Colitis

A Clinical Trial to Compare Etrolizumab with Infliximab in Patients with Moderate to Severe Ulcerative Colitis Who Have not Received Treatment with Tumour Necrosis Factor Inhibitors (Gardenia)

Phase III, randomized, multicenter double-blind, double dummy study to evaluate the efficacy and safety of Etrolizumab compared with Infliximab in patients with moderate to severe active Ulcerative Colitis who are naïve to TNF inhibitors

Trial Status	Trial Runs In	Trial Identifier
Completed	20 Countries	NCT02136069 2013-004282-14 GA29103

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

Phase III, Randomized, Multicenter Double-Blind, Double Dummy Study to Evaluate the Efficacy and Safety of Etrolizumab Compared With Infliximab in Patients With Moderate to Severe Active Ulcerative Colitis Who Are Naive to TNF Inhibitors

Trial Summary:

This is a multicenter, Phase III, randomized, double-blind, double-dummy, parallel-group study to evaluate the safety, efficacy, and tolerability of etrolizumab compared with infliximab in treating participants with moderate to severe ulcerative colitis (UC) who are naive to tumor necrosis factor (TNF) inhibitors. Participants will be randomized in a 1:1 ratio to receive either etrolizumab 105 milligrams (mg) by subcutaneous (SC) injection once every 4 weeks (Q4W) + placebo (intravenous [IV] infusion at Weeks 0, 2, and 6, then once every 8 weeks [Q8W]) or infliximab 5 milligrams/kilogram (mg/kg) IV at Weeks 0, 2, and 6, then Q8W) + placebo (SC Q4W). Time on treatment is 54 weeks.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT02136069 2013-004282-14 GA29103
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

All	# 18 Years & # 80 Years	No

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

How do I take part in this clinical trial? To be able to take part in this trial, you must not have already been given a type of medicine called a ‘tumour necrosis factor inhibitor’ for your ulcerative colitis.

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.

Before starting the clinical trial, 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. Both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or to take contraceptive medication 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 two groups randomly (like flipping a coin) and given one of two different treatments. This is a ‘placebo-controlled’ clinical trial, which means that patients will also be given a treatment with no active drug (also known as a placebo). You will have a 1 in 2 chance of being given each treatment.

- Either you will be given an injection of etrolizumab under the skin and a placebo given into your vein (called an ‘intravenous infusion’).
- Or you will be given infliximab into your vein and an injection under the skin of a placebo.

How often will I be seen in follow-up appointments, and for how long? Etrolizumab or the placebo injection under the skin will be given once every 4 weeks during the 1 year long treatment part of the clinical trial. If appropriate, you may be able to administer the

etrolizumab or placebo injection yourself at home after a period of training. Infliximab or the placebo infusion will be given at the clinical trial site once on Weeks 0, 2, and 6, and then every 8 weeks during the 1 year long treatment part of the clinical trial.

If you take part in this clinical trial, you will be asked to keep an electronic diary at home to record how you are feeling and managing with day-to-day tasks. You will need to go to the clinical trial site to assess your general health and how your body is responding to the treatment (and to be given the infusions). 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.

If you withdraw from the trial because your symptoms of ulcerative colitis have got worse or for any other reason, you may be given the chance to take part in another clinical 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 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/record/NCT02136069

Trial-identifier: NCT02136069

Inclusion Criteria:

- Moderately to severely active UC as determined by the Mayo Clinic Score assessment (MCS)
- Naive to treatment with any anti-TNF inhibitor therapy (including TNF inhibitor biosimilars)
- An inadequate response to or intolerance of prior corticosteroid and/or immunosuppressant treatment
- Background regimen for UC may include oral 5-aminosalicylate (5-ASA), oral corticosteroids, budenoside multi-matrix system (MMX), probiotics, azathioprine (AZA), 6-mercaptopurine (6-MP), or methotrexate (MTX) if doses have been stable during the screening period
- Use of highly effective contraception during and at least 24 weeks after the last dose of study drug

Exclusion Criteria:

- A history of or current conditions and diseases affecting the digestive tract, such as indeterminate colitis, suspicion of ischemic, radiation or microscopic colitis, Crohn's disease, fistulas or abdominal abscesses, colonic mucosal dysplasia, intestinal obstruction, toxic megacolon, or unremoved adenomatous colonic polyps
- Prior or planned surgery for UC
- Past or present ileostomy or colostomy

- Have received non-permitted inflammatory bowel disease (IBD) therapies (including natalizumab, vedolizumab, efalizumab, and tofactinib)
- History of moderate or severe allergic or anaphylactic/anaphylactoid reactions to chimeric, human, or humanized antibodies; fusion proteins, or murine proteins; hypersensitivity to etrolizumab or any of its excipients
- Chronic hepatitis B or C infection, Human deficiency virus (HIV) or tuberculosis (active or latent)