ForPatients
by Roche

Crohn's Disease

A Clinical Trial of Etrolizumab for Patients with Moderately to Severely Active Crohn's Disease (Bergamot)

A Study to Assess Whether Etrolizumab is a Safe and Effective Treatment for Participants With Moderately to Severely Active Crohn's Disease (Bergamot)

Trial Status	Trial Runs In	Trial Identifier
Completed	0 Countries	NCT02394028 2014-003824-36 GA29144

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 is a multicenter, Phase 3, double-blind, placebo-controlled study evaluating the efficacy, safety, and tolerability of etrolizumab compared with placebo during induction and maintenance treatment of moderately to severely active Crohn's Disease (CD). The target population includes participants with CD who are refractory or intolerant to corticosteroids (CS) and/or immunosuppressant (IS) therapy and who have either not received prior anti-tumor necrosis factor (anti-TNF) therapy (TNF-naive) or who have had prior exposure to anti-TNF therapies and demonstrated inadequate responses or intolerance to anti-TNFs. The study period will consist of a Screening Phase (up to 35 days) plus (+) a 14-week Induction Phase + a 52-week Maintenance Phase + a 12-week Safety Follow-up Phase. At Week 14 (end of Induction Phase), participants achieving a decrease from baseline of at least 70 points in the Crohn's Disease Activity Index (CDAI) score (CDAI-70 response) without the use of rescue therapy will continue to the Maintenance Phase.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT02394028 2014-003824-36 GA29144
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>= 18 Years & <= 80 Years	No

How does the Bergamot clinical trial work?

This clinical trial is recruiting adults who have ‘Crohn’s disease’, a condition that results in inflammation and ulcers in the part of the gut called the ileum (part of the small intestines) or in the colon. It is for people whose Crohn’s disease is categorised as moderately to severely active.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have Crohn’s disease that has already been treated with corticosteroids, immunosuppressants, or a type of medicine called a ‘tumour necrosis factor inhibitor’ and at least one of these types of medicines are no longer working, or you cannot continue taking them due to side effects.

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 receive 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 four parts or ‘phases’. These phases are called the:

- ‘Screening phase’ where the clinical trial doctor will check your suitability for the trial; this lasts for up to 5 weeks.
- ‘Induction phase’ where you will be given the trial treatment; this lasts for up to 14 weeks.
- ‘Maintenance phase’ as long as you have responded to the treatment by Week 14 of the induction phase, you will receive further trial treatment; this lasts for up to 52 weeks.
- ‘Safety-monitoring follow-up phase’ where the clinical trial doctor will check if you are having any side effects; this lasts for 12 weeks and you will not receive any trial treatment during this phase.

The maximum length of time you will be in this clinical trial is 83 weeks. After this clinical trial, you may be able to enter another clinical trial, called Juniper, where you will only receive treatment with active etrolizumab (not placebo).

What happens during the screening phase?
During the screening phase, you will be told about any risks and possible 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) must take precautions not to become pregnant while taking part in the trial for safety reasons.

What treatment will I be given if I join this clinical trial?

This is a 'placebo-controlled' clinical trial, which means that an injection with no active drug (also known as a placebo) will be given to some patients.

Induction phase Everyone who joins this clinical trial will be entered into one of three groups; patients in each of the three groups will be split randomly (like flipping a coin) between the different treatments:

- Group 1 will be given an injection of placebo or etrolizumab 105 mg (low dose) every 4 weeks or etrolizumab 210 mg (high dose) at Weeks 0, 2, 4, 8 and 12. You will have a 2 in 5 chance of being given the low dose of etrolizumab, a 2 in 5 chance of being given the high dose of etrolizumab and a 1 in 5 chance of being given placebo. Please note that Group 1 is now closed.
- Group 2 will be given an injection of etrolizumab 105 mg (low dose) every 4 weeks or etrolizumab 210 mg (high dose) at Weeks 0, 2, 4, 8 and 12. You will have a 1 in 2 chance of being given the low dose of etrolizumab and a 1 in 2 chance of being given the high dose of etrolizumab. Please note that Group 2 is now closed.
- Group 3 will be given an injection of placebo or etrolizumab 105 mg (low dose) every 4 weeks or etrolizumab 210 mg (high dose) at Weeks 0, 2, 4, 8 and 12. You will have a 3 in 8 chance of being given the low dose of etrolizumab, a 3 in 8 chance of being given the high dose of etrolizumab and a 2 in 8 chance of being given placebo.

For patients who do not respond to treatment in the induction phase your doctor will talk to you about entering the Juniper clinical trial, where you will only be given treatment with active etrolizumab (not placebo), as long as your doctor considers you to be suitable for this. The clinical trial doctor will give you all the information you need to make your decision about taking part in this other clinical trial.

Maintenance phase All patients who respond to treatment (based on certain criteria) in the induction phase will go into the maintenance phase. In the maintenance phase, you may receive a different trial treatment to the one you received in the induction phase. You will have a 1 in 2 chance of being given an injection of placebo and a 1 in 2 chance of being given an injection of etrolizumab 105 mg (low dose) every 4 weeks for up to 52 weeks. After you finish the maintenance phase, you may be suitable to enter the Juniper clinical trial, where you will only be given treatment with active etrolizumab (not placebo). Your clinical trial doctor will give you the information you need to make your decision about taking part in this other trial.

To allow a fair comparison between the low dose and the high dose of etrolizumab, 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 treatment you are being given.

How often will I be seen in follow-up appointments, and for how long? During the induction and maintenance phases, you will be asked to keep an electronic diary at home to record how you are feeling and managing with day-to-day activities. The induction phase lasts for up to 14 weeks, and you will come the hospital at the beginning (Week 0), and then at Weeks 2, 4, 8, 10, 12 and 14 to be given your medicine and be assessed for your Crohn's disease. The clinical trial doctor will ask you about how your Crohn's disease is responding to the treatment and about any side effects that you may be having. During the induction phase, you will be trained to administer the trial treatment yourself at the clinic.

The maintenance phase lasts for up to 52 weeks, and you will have the option to either return to the clinic or have telephone visits and administer the injection yourself at home every 4 weeks. Alternatively, a caregiver may be trained to administer the trial treatment to you at home.

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 (Juniper) with etrolizumab will 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. If you decide to participate in this clinical trial, you can withdraw at any time for any reason and your care will not be affected.

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

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