

Follicular Lymphoma

A Clinical Trial to Investigate the Effect of a Short Duration Infusion of Obinutuzumab in Patients with Previously Untreated Advanced Follicular Lymphoma (MO40597 study)

An Open-Label, Single Arm Study of Obinutuzumab Short Duration Infusion in Patients With Previously Untreated Advanced Follicular Lymphoma (MO40597 study)

Trial Status
Completed

Trial Runs In
7 Countries

Trial Identifier
NCT03817853 MO40597

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 open-label, single arm study will evaluate the safety of obinutuzumab administered as a short duration infusion (SDI; target 90-minute infusion) during cycle 2 and from cycle 2 onwards in combination with chemotherapy in participants with previously untreated advanced follicular lymphoma (FL). The study has two phases: in the first phase, participants will receive the first cycle of obinutuzumab-based chemotherapy (G-chemo) induction therapy as usual with the first three infusions of obinutuzumab (1000 mg) administered at the regular infusion rate on Day 1, 8, and 15 of cycle 1. Phase 2 starts when participants who do not experience any Grade # 3 infusion related reactions during the first cycle receive their first obintuzumab infusion given at the faster infusion rate in Cycle 2. For Cycle 2, Day 1 and all other following infusions (including maintenance), obinutuzumab will be administered at a faster infusion of 90-minute SDI, as long as the participant does not experience any Grade # 3 infusion related reactions. The investigator is free to choose the chemotherapy for each participant (bendamustine, CHOP [cyclophosphamide, doxorubicin, vincristine, prednisone/prednisolone/methylprednisolone], or CVP [cyclophosphamide, vincristine, and prednisone/prednisolone/methylprednisolone]). The total number of cycles of G-chemo induction therapy and the cycles length depends on the chemotherapy chosen for each participant.

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Phase 4
Phase

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Trial Identifiers

Eligibility Criteria:

Gender All	Age >=18 Years	Healthy Volunteers No
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How does the MO40597 clinical trial work? This clinical trial is recruiting people who have a specific type of blood cancer called 'follicular lymphoma'. This type of cancer is caused by cells that usually fight infection called white blood cells (or immune cells) that multiply out of control.

This study is testing whether an approved medicine called obinutuzumab can be given through a drip into the vein (called an intravenous infusion) at a faster infusion rate, so that the obinutuzumab infusion is given within approximately 90 minutes instead of the usual 4 hours (i.e. regular infusion rate).

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 any medicine for your cancer.

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 tests to make sure you will be able to take the treatments given in this clinical trial. These are the same tests that you would have as part of your regular care for follicular lymphoma, regardless of whether you take part in this study or not. If you have had some of these 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. While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to agree to either not have heterosexual intercourse or use contraceptive methods for safety reasons whilst receiving treatment and for some time afterwards. If you are a woman and decide to use contraceptive methods, you will need to continue using contraception up to 18 months after last clinical trial treatment. If you are pregnant you will not be able to participate in this clinical trial. If you are a man and decide to use contraceptive methods, you will need to continue using contraception up to 3 months after clinical trial last treatment.

What treatment will I be given if I join this clinical trial? All patients in this study will be given a treatment called obinutuzumab and chemotherapy. Which chemotherapy you receive will be decided by the clinical trial doctor. Before your treatment begins, you will be given a combination of medicines (called premedication) that will reduce the risk of having side effects to obinutuzumab and chemotherapy.

- For the first part of the study, everyone will receive obinutuzumab and chemotherapy every 3 to 4 weeks (1 cycle) for 24 to 32 weeks (6 to 8 cycles). This is called 'induction' therapy. Your doctor will decide which chemotherapy is best for you.
- During the first cycle of treatment, everyone will receive obinutuzumab on Days 1, 8 and 15. For every following cycle, you will receive obinutuzumab on Day 1 only.
- This first cycle of obinutuzumab treatment will be given at the regular infusion rate (4 hours) and doctors will look for any side effects (known as infusion-related reactions). To reduce the chance that you experience an infusion-related reaction, the clinical trial doctor may give you some premedication (acetaminophen, to reduce fever and chills, and an antihistamine and a corticosteroid) before the infusion.
- Infusion related reactions may include fever (high body temperature), chills (cold shivers), rash, low blood pressure, and difficulty breathing, among others. Most infusion-related reactions are mild or moderate, but severe, life-threatening reactions can occur.
- If you do not have any infusion-related reactions (or they were very mild), your second cycle of treatment will be given at a faster infusion rate (approximately 90 minutes). This will continue for the rest of the infusions you receive in the study as long as you do not have any infusion-related reactions in later cycles.
- If you experience a moderate or severe infusion-related reaction, your next cycle of treatment will remain at the regular infusion rate (4 hours). Your doctor may increase the speed of treatment in later cycles if they feel it is safe to do so.
- If your disease is responding to the treatment after completing the induction therapy, you will receive additional treatment with obinutuzumab alone (i.e. without chemotherapy) every 8 weeks for up to 2 years at the faster infusion rate. This is called 'maintenance therapy'.
- If at any stage your cancer does not respond to the treatment, or you experience life threatening side effects, your doctor may decide to stop the treatment and you will enter the safety-monitoring follow-up phase where you will be seen once by the clinical trial doctor 3 months after you receive your last treatment.

How often will I be seen in follow-up appointments, and for how long? You will be given the trial treatment for as long as it can help you for up to 2 years. You are free to stop this treatment at any time. During your treatment, you will be seen regularly by the clinical trial doctor to see how your cancer is responding to the treatment and if you are experiencing any side effects. After you receive your last treatment, your next and final study visit will be 3 months later when you will be seen by the clinical trial doctor. This will include a hospital visit where you will be given a physical examination, a scan, blood tests and to talk about how your cancer is responding to the treatment and any side effects that

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you may be having. The total length of time you will be on the study is just over two and a half years.

What happens if I'm unable to take part in this clinical trial? If your specific cancer type does not match what this clinical trial is looking at and/or the results of your blood tests are not in the range needed for the trial, you will not be able to take part in this clinical trial. Your doctor will suggest other treatments for your cancer 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)