

ForPatients

by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)

A clinical trial to compare glofitamab plus chemotherapy with rituximab plus chemotherapy in people with diffuse large B-cell lymphoma (after previous treatment has not worked).

A Phase III Study Evaluating Glofitamab in Combination With Gemcitabine + Oxaliplatin vs Rituximab in Combination With Gemcitabine + Oxaliplatin in Participants With Relapsed/Refractory Diffuse Large B-Cell Lymphoma

Trial Status Active, not recruiting	Trial Runs In 14 Countries	Trial Identifier NCT04408638 2020-001021-31 GO41944
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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 study will evaluate the efficacy and safety of glofitamab in combination with gemcitabine plus oxaliplatin (Glofit-GemOx) compared with rituximab in combination with gemcitabine plus oxaliplatin (R-GemOx) in patients with R/R DLBCL.

Hoffmann-La Roche Sponsor	Phase 3 Phase
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NCT04408638 2020-001021-31 GO41944
Trial Identifiers

Eligibility Criteria:

Gender All	Age ≥18 Years	Healthy Volunteers No
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How does the GO41944 clinical trial work?

This clinical trial is recruiting people who have a type of disease called diffuse large B-cell lymphoma, or DLBCL. In order to take part, patients must have DLBCL that is relapsed or refractory.

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The purpose of this clinical trial is to compare the effects, good or bad, of glofitamab plus chemotherapy versus rituximab plus chemotherapy on patients with relapsed or refractory DLBCL.

In this clinical trial, you will get either glofitamab plus two chemotherapy drugs (gemcitabine and oxaliplatin, often shortened to GemOx) or rituximab plus GemOx.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have been diagnosed with DLBCL that has not improved within 6 months of completing your last treatment (refractory), or has come back after a minimum of 6 months from completing your last treatment (relapsed). If you have only received one previous course of treatment, your doctor must also make sure that you are not a candidate for bone marrow transplant.

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. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on 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 or procedures may be part of your regular medical care. They 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. You will also be told what other treatments are available so that you may decide if you still want to take part.

If you or your partner are able to become pregnant, your doctor will talk to you about requirements for contraception (or alternatively abstaining from sexual intercourse) during the clinical trial.

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

The treatments in this clinical trial will be given in 'cycles', with each cycle lasting for 3 weeks (21 days). Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin).

Patients in the glofitamab plus GemOx group will receive:

- Obinutuzumab (pretreatment to reduce the side effects of glofitamab) given as an infusion into the vein on Day 1 of cycle 1
- Gemcitabine and oxaliplatin given as an infusion into the vein on Day 2 of cycle 1 and then on Day 1 or Day 2 of subsequent cycles, for up to 8 cycles in total

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- Glofitamab, given as an infusion into the vein on Day 8 and Day 15 of cycle 1, and then on Day 1 of each of the next 11 cycles

Patients in the rituximab plus GemOx group will receive:

- Rituximab, given as an infusion into the vein on Day 1 of each cycle for up to 8 cycles
- Gemcitabine and oxaliplatin on Day 2 of cycle 1 and then on Day 1 or Day 2 of subsequent cycles, for up to 8 cycles in total

You will have a 2 in 3 chance of being entered into the glofitamab plus GemOx group, and a 1 in 3 chance of being entered into the rituximab plus GemOx group.

How often will I be seen in follow-up appointment and for how long?

You will be given the clinical trial treatment glofitamab for up to 12 cycles or rituximab for up to 8 cycles, plus up to 8 cycles of GemOx chemotherapy. You are free to stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor every 3 months. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

What happens if I am 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 clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov <https://clinicaltrials.gov/ct2/show/NCT04408638>

Trial-identifier: NCT04408638