ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)

A clinical trial to compare glofitamab plus Pola-R-CHP with Pola-R-CHP alone in people with untreated large B-cell lymphoma

An Open-Label Study Comparing Glofitamab and Polatuzumab Vedotin + Rituximab, Cyclophosphamide, Doxorubicin, and Prednisone Versus Pola-R-CHP in Previously Untreated Patients With Large B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Recruiting	20 Countries	NCT06047080 GO44145

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

Trial Summary:

The purpose of this study is to compare the efficacy and safety of glofitamab in combination with polatuzumab vedotin plus rituximab, cyclophosphamide, doxorubicin, and prednisone (Pola-R-CHP) vs Pola-R-CHP in participants with previously untreated CD20-positive large B-cell lymphoma (LBCL).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT06047080 GO44145
Trial Identifiers

Eligibility Criteria:

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

1. Why is the GO44145 clinical trial needed?

Large B-cell lymphoma (LBCL) is the most common type of non-Hodgkin lymphoma. Lymphoma is a type of cancer that starts in white blood cells called lymphocytes. Lymphocytes help protect the body from infection but in LBCL, B-cell lymphocytes become abnormal and collect in the lymph nodes and spleen. This causes lymph nodes to swell and form cancerous tumours. The standard first treatment for LBCL is a combination of chemotherapy and immunotherapy. Immunotherapies are medicines that help the body to use its immune system to fight the cancer. Pola-R-CHP is a standard first treatment

that combines polatuzumab vedotin (pola) plus rituximab (R), cyclophosphamide (C), doxorubicin (H), and prednisone (P). For some people, their cancer does not respond to treatment, or it comes back after their first treatment. Glofitamab is an experimental drug that attaches to a protein called CD20 that is found on some types of LBCL cells. It can join to another protein on cancer-killing cells of the immune system. This brings them closer together so immune cells destroy the LBCL cells. Glofitamab plus Pola-R-CHP may work better as a first treatment than Pola-R-CHP alone for LBCL that has CD20. This clinical trial aims to compare the effects, good or bad, of glofitamab plus Pola-R-CHP versus Pola-R-CHP alone in people with LBCL.

2. How does the GO44145 clinical trial work?

This clinical trial is recruiting people with a health condition called LBCL. People can take part if they have untreated CD20-positive LBCL. People who take part in this clinical trial (participants) will be given the clinical trial treatment glofitamab plus Pola-R-CHP or Pola-R-CHP alone. Treatment will last for about 6 months (24 weeks). The clinical trial treatment is given in eight 21-day ‘cycles’; a cycle is the treatment and recovery time. To reduce the chance of side effects from glofitamab treatment, participants will build up to the intended target dose (called ‘step-up’ doses). The clinical trial doctor will see participants while treatment is being given and about one month after the last dose of treatment. Hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The clinical trial doctor will then follow up with participants about every 3 months by telephone for as long as agreed to. There will be ongoing long-term follow up which will include scans, telephone calls, and questionnaires. The total time in the clinical trial will be approximately 3 years. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the GO44145 clinical trial?

The main clinical trial endpoint (the main result measured in the trial to see if the drug has worked) is the length of time between the start of the trial and a participant’s cancer getting worse, if applicable (known as ‘progression-free survival’, or PFS).

The other clinical trial endpoints include:

- The time between starting the trial and having a change in disease or treatment (event-free survival)
- How many participants have no signs of cancer (complete response rate)
- How many participants have a smaller tumour size after treatment (objective response rate)
- How long participants live after treatment (overall survival)
- The time between participants’ cancer getting better from treatment and then getting worse (duration of response) or having no signs of cancer and then cancer getting worse (duration of complete response)

- The number and seriousness of any side effects
- How the body processes the clinical trial treatment
- The number of participants who have positive or negative effects of treatment on their health

4. Who can take part in this clinical trial?

People can take part in this trial if they are aged 18 to 80 and have LBCL with the CD20 marker. Participants must also have an IPI score of 2–5. This is a scale of 1–5 which aids in predicting the prognosis of patients. Participants need to be willing to allow a sample of their tumour to be checked for CD20.

People may not be able to take part in this trial if they:

- Have received previous treatment for LBCL (except steroids for symptom control)
- Have had treatment for any condition with immunotherapy medicine shortly before the trial
- Have or had medical conditions including lymphoma and viral infections (such as HIV, hepatitis B or C, cancers, heart disease or liver disease, organ transplant or recent major surgery
- Are pregnant or breastfeeding, or are planning to become pregnant during the trial

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin) and given either:

Group A: Glofitamab and Pola-R-CHP

- Glofitamab will be given in two increasing doses as an infusion (into the vein) in Cycles 2–8
- Pola, -R, -C, and H from pola-R-CHP will be given as an infusion (into the vein) in Cycles 1–6

Group B: Pola-R-CHP alone

- Pola, -R, -C, and H from pola-R-CHP will be given as an infusion (into the vein) in Cycles 1–6
- Rituximab (part of Pola-R-CHP) only will be given in Cycles 7 and 8 as an infusion (into the vein)

In both groups, prednisone (P) will be given as a pill (to be swallowed), or may be replaced with prednisolone (given as a pill), or with methylprednisolone (given as an infusion) . If a participant experiences a potential side effect called ‘cytokine release syndrome’ (inflammatory throughout the body), they may receive another medicine called tocilizumab. This is an open-label trial, which means everyone involved, including the

participant and the clinical trial doctor, will know the clinical trial treatment the participant has been given.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly. Participants will be told about the known side effects of **glofitamab, polatuzumab vedotin, rituximab, cyclophosphamide, doxorubicin, prednisone/prednisolone/methylprednisolone** and **tocilizumab** and possible side effects based on human and laboratory studies or knowledge of similar drugs. **Glofitamab, polatuzumab vedotin, rituximab, cyclophosphamide, doxorubicin, methylprednisolone** and **tocilizumab** will be given by infusion (into the vein). Participants will be told about any known side effects of infusion or . **Prednisone/prednisolone** will be given as a pill (to be swallowed). Participants will be told about any known side effects of swallowing pills.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.