ForPatients
by Roche

Diffuse Large B-Cell Lymphoma (DLBCL)

A clinical trial to compare how well treatment with polatuzumab vedotin plus rituximab plus gemcitabine plus oxaliplatin (Pola-R-GemOx) works in people with diffuse large B-cell lymphoma versus treatment with R-GemOx alone

A Study to Evaluate the Safety and Efficacy of Polatuzumab Vedotin in Combination With Rituximab, Gemcitabine and Oxaliplatin Compared to Rituximab, Gemcitabine and Oxaliplatin Alone in Participants With Relapsed or Refractory Diffuse Large B-Cell Lymphoma

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	17 Countries	NCT04182204 2018-003727-10 MO40598

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 is a multicenter, open-label study of polatuzumab vedotin administered by intravenous (IV) infusion in combination with rituximab, gemcitabine and oxaliplatin (R-GemOx) in participants with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). The study comprises of two stages: a safety run-in stage and a randomized controlled trial (RCT).

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

NCT04182204 2018-003727-10 MO40598
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

Why is the POLARGO clinical trial needed?

New treatments are needed for people who have a particular type of lymphoma called diffuse large B-cell lymphoma (DLBCL) that has not responded to, or has returned after,

previous treatment. In previous clinical trials, standard lymphoma treatments have been shown to work better when given with a drug called polatuzumab vedotin. This trial will assess if a standard treatment called R-GemOx (which is rituximab plus gemcitabine plus oxaliplatin) works better when given with polatuzumab vedotin (all together referred to as Pola-R-GemOx), compared with R-GemOx alone.

How does the POLARGO clinical trial work?

This clinical trial is recruiting people who have a health condition called DLBCL. People can take part if they have:

- DLBCL that improved at first with treatment but has returned afterwards (known as relapsed DLBCL), or
- DLBCL that has not improved with treatment (known as refractory DLBCL)

The purpose of this clinical trial is to compare the effects, good or bad, of Pola-R-GemOx versus R-GemOx in people with DLBCL. People who take part in this clinical trial will receive either Pola-R-GemOx or R-GemOx.

Pola-R-GemOx treatment has been shown to have a good safety profile when assessed in a small number of people with DLBCL. This trial will now assess safety, and how well Pola-R-GemOx works, in a larger number of people with DLBCL.

What are the main endpoints of the POLARGO clinical trial?

The main clinical trial endpoints (the main results that are measured in the trial to see if the medicine has worked) are how long participants live (overall survival), and the safety of Pola-R-GemOx as measured by the number and type of side effects that participants experience.

The other clinical trial endpoints include:

- The percentage of participants who have no detectable cancer (complete response) at the end of treatment
- The percentage of patients who have either no detectable cancer or who have cancer that has reduced in size at the end of treatment (objective response rate)
- The time from the start of the trial to the first sign that the cancer has started to grow or spread (progression-free survival)

Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years of age and have been diagnosed with either relapsed or refractory DLBCL.

People may not be able to take part in this trial if they have certain medical conditions or have previously received certain treatments, including polatuzumab vedotin. Women cannot take part in this trial if they are pregnant or breastfeeding, or are planning to become pregnant soon after the clinical trial.

What treatment will participants be given in this clinical trial?

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

- Pola-R-GemOx given as an infusion into the vein, every 3 weeks, for up to 6 months (eight rounds [also called 'cycles'] of treatment), OR
- R-GemOx given as an infusion into the vein every 3 weeks, for up to 6 months (eight cycles of treatment)

For participants being given Pola-R-GemOx, the polatuzumab vedotin and rituximab infusions will be given on the same day, which will take 3–6 hours, and gemcitabine and oxaliplatin will be given on the following day over 2.5–6 hours.

For participants being given R-GemOx, the rituximab infusion will be given on one day and will take 1.5–4 hours, and gemcitabine and oxaliplatin will be given on the following day over 2.5–6 hours.

Participants will have an equal chance of being placed in either group.

Neither participants nor the clinical trial doctor can choose the group participants are in. However, the trial is open-label, which means that both participants and the clinical trial doctor will know which treatment participants have been given.

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, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants 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. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the 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 and even life-threatening, and can vary from person to person.

Pola-R-GemOx or R-GemOx

Potential participants will be told about the known side effects of polatuzumab vedotin, rituximab, gemcitabine, and oxaliplatin, and where relevant, also potential side effects, based on human and laboratory studies or knowledge of similar drugs.

Pola-R-GemOx and R-GemOx will be given as an infusion into the vein. Participants will be told about any known side effects of intravenous infusions.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04182204