ForPatients
by Roche

Lupus Nephritis

A clinical trial to compare obinutuzumab with placebo in adolescents with lupus nephritis (POSTERITY)

A Study to Evaluate the Efficacy, Safety, and Pharmacokinetics of Obinutuzumab in Adolescents With Active Class III or IV Lupus Nephritis and the Safety and PK of Obinutuzumab in Pediatric Participants

Trial Status	Trial Runs In	Trial Identifier
Recruiting	12 Countries	NCT05039619 2021-000097-29,2023-505825-15-00 WA42985

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 phase II, randomized, double-blind, placebo-controlled study is designed to evaluate the safety, efficacy and pharmacokinetics (PK) of obinutuzumab in adolescent participants (AP) aged 12 to less than 18 with biopsy-confirmed proliferative lupus nephritis (LN). It will also evaluate open label safety and PK of obinutuzumab in pediatric participants (PP), aged 5 to <12 with LN.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT05039619 2021-000097-29,2023-505825-15-00 WA42985
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=5 Years & <= 17 Years	No

How does the POSTERITY (WA42985) clinical trial work?

This clinical trial is recruiting adolescents who have active lupus nephritis (LN).

The purpose of this clinical trial is to compare the effects, good or bad, of obinutuzumab against placebo in patients with lupus nephritis. If you take part in this clinical trial, you will receive either obinutuzumab or placebo (a substance that looks like obinutuzumab but

contains no active ingredients), in addition to your usual treatment of corticosteroids and mycophenolate mofetil (MMF).

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 12 years old and less than 18 years old at the start of the clinical trial, have been diagnosed with lupus nephritis according to certain criteria, and have been treated with at least one dose of intravenous (into the vein) methylprednisolone (or similar) in the last 12 months.

You must not have severe, active central nervous system systemic lupus erythematosus (SLE) or severely damaged kidneys, according to certain criteria. If you have an active infection or are taking certain medications, you may not be able to take part in this clinical trial.

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, they 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.

While taking part in the clinical trial, both male and female patients (who are not currently pregnant but could become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

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

Everyone who joins this clinical trial will enter a screening/observation period to make sure they are able to take part. Patients will be split into two groups randomly (like flipping a coin) and given either:

- Obinutuzumab as an infusion into the vein on Days 1 and 14, then six months later at Weeks 24 and 26 and again six months later at Week 52
- OR placebo as an infusion into the vein on Days 1 and 14, then six months later at Weeks 24 and 26, and again six months later at Week 52.

You will have a 2 in 3 chance of being placed in the obinutuzumab group and a 1 in 3 chance of being placed in the placebo group. No matter which group you are placed in, you will still receive corticosteroids and MMF treatment every day for your lupus nephritis, as tablets to be swallowed.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a ‘placebo’). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in if your safety is at risk.

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

You will be given the clinical trial treatment obinutuzumab or placebo for roughly 18 months. You are free to stop this treatment at any time. You will be seen regularly by the clinical trial doctor in 11 visits over the 18-month period. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. Safety follow-up visits after your last infusion of clinical trial treatment will occur every six months for at least 12 months. You may need to make additional visits if your clinical trial doctor feels it is necessary.

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

Trial-identifier: NCT05039619