ForPatients
by Roche

Membranous Nephropathy Primary Membranous Nephropathy

A clinical trial to compare obinutuzumab with tacrolimus in people with a kidney disease called primary membranous nephropathy.

A Study Evaluating the Efficacy and Safety of Obinutuzumab in Participants With Primary Membranous Nephropathy

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	12 Countries	NCT04629248 2020-003233-38, 2023-506525-11-00 WA41937

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, safety, pharmacodynamics, and pharmacokinetics (PK) of obinutuzumab compared with tacrolimus in participants with primary membranous nephropathy (pMN).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04629248 2020-003233-38, 2023-506525-11-00 WA41937
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 75 Years	No

How does the WA41937 (MAJESTY) clinical trial work? This clinical trial is recruiting people who have a particular type of kidney disease called primary membranous nephropathy (pMN).

The purpose of this clinical trial is to compare the effects of obinutuzumab against tacrolimus in patients with pMN. If you take part in this clinical trial, you will receive either obinutuzumab or tacrolimus.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must be diagnosed with pMN. You must also have a certain level of kidney function and blood pressure.

You must not have been diagnosed with diabetes or have this type of kidney disease as a result of another condition e.g. cancer. If you have previously received certain medications within a certain amount of time, you may not be able to take part. If you are pregnant or breastfeeding you will not be able to take part.

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.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or use contraception for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be split into 2 groups randomly (like flipping a coin) and given one of the following treatments:

- Obinutuzumab, given as an infusion into the vein. This will be given on the first day of treatment and then repeated at Week 2, Week 24 and Week 26
- Tacrolimus, given as a capsule to take by mouth twice a day (every 12 hours) for a maximum of 14 months

You will have an equal chance of being placed in any group and you and your doctor will know which treatment you are receiving.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment obinutuzumab for 4 doses OR tacrolimus for a maximum of 14 months. During the treatment period, clinical trial staff will see you at regular clinic visits at the hospital, or nursing staff may visit you at your home. These visits will include checks to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After finishing the treatment period, you will still have regular follow up with the clinical trial staff for up to 2 years or more.

If you do not respond to treatment or if you got better initially but then became worse again, you will be given the option to receive further doses of obinutuzumab or treatment with obinutuzumab and tacrolimus.

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: NCT04629248