ForPatients
by Roche

Renal Failure Chronic Renal Failure Chronic Kidney Disease

A Study of Obinutuzumab to Evaluate Safety and Tolerability in Hypersensitized Adult Participants With End Stage Renal Disease Awaiting Transplantation

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Countries	NCT02586051 WT29749

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 is a Phase Ib, open-label study of single and repeat doses of obinutuzumab administered as intravenous (IV) infusion in adults with end stage renal disease (ESRD). Participants will be enrolled into two cohorts receiving either one (Cohort 1) or two or more (Cohort 2) obinutuzumab infusions. Both cohorts will receive standard pretreatments to reduce the risk of infusion-related reactions (IRRs). Desensitization Period: In Cohort 1, participants will receive single dose obinutuzumab IV infusion on Day 1. Following review of Cohort 1 aggregated safety data up to 4 weeks post dose for the last participant of Cohort 1, Cohort 2 will be allowed to proceed. In Cohort 2, participants will receive obinutuzumab IV infusion on Days 1 and 15. Transplantation Period: Participants who qualify for transplantation and receive a compatible kidney offer after inclusion in Cohort 1 or Cohort 2 will receive two additional infusions (one at the time of transplantation and second at Week 24 post-transplantation) of obinutuzumab. Assessment of the safety and tolerability of the obinutuzumab regimen will be conducted at Week 24 of the desensitization phase and at Week 28 post-transplantation. All participants will be monitored for a minimum of 12 months following the last obinutuzumab infusion.

Hoffmann-La Roche
Sponsor

Phase 1
Phase

NCT02586051 WT29749
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 65 Years	No