ForPatients
by Roche

Non Hodgkin Lymphoma (NHL)

A study to look at whether longer rituximab treatment provides additional benefit in patients with non-Hodgkin lymphoma and whether this affects treatment safety (the MabCute study)

A Study Comparing Maintenance Subcutaneous Rituximab With Observation Only in Participants With Relapsed or Refractory Indolent Non-Hodgkin's Lymphoma Who Had Responded to Rituximab-based Immunochemotherapy Induction and 2-year Maintenance With Subcutaneous Rituximab

Trial Status	Trial Runs In	Trial Identifier
Completed	24 Countries	NCT01461928 2010-023407-95 MO25455

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 multicenter, randomized, open-label, parallel-group study will evaluate the efficacy and safety of subcutaneously administered rituximab in comparison with observation only as maintenance therapy in participants with relapsed or refractory indolent Non-Hodgkin's lymphoma (NHL). All participants will receive induction therapy with rituximab (375 milligrams per square meter [mg/m^2] intravenously [IV] in Cycle 1, then 1400 mg subcutaneous [SC] every 3-4 weeks) plus standard chemotherapy for 6-8 months; followed by 24 months of maintenance I period with rituximab (1400 mg SC every 8 weeks). Participants completing therapy and showing partial or complete response will be randomized to receive either rituximab (1400 mg SC every 8 weeks) or observation with no treatment during maintenance II period and will be followed for at least 15 months. Anticipated time on study treatment is until disease progression, unacceptable toxicity or end of study, whichever occurs first.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT01461928 2010-023407-95 MO25455
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

ForPatients
by Roche

All	>=18 Years	No