ForPatients
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Non-Hodgkin-Lymphom

Eine Studie zum Vergleich einer Erhaltungstherapie mit subkutanem Rituximab gegenüber der reinen Anwendungsbeobachtung bei Teilnehmenden mit rezidiviertem oder refraktärem indolentem Non-Hodgkin-Lymphom, die auf die Rituximab-basierte Induktionsbehandlung mittels Immunchemotherapie und eine zweijährige Erhaltungstherapie mit subkutanem Rituximab angesprochen hatten

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 (MabCute)

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

Die Informationen stammen direkt von Websites öffentlicher Register wie ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com usw. und wurden nicht modifiziert.

Official Title:

A Randomized Study Comparing Maintenance Therapy With Subcutaneous Rituximab Continued Until Progression With Observation Only in Patients With Relapsed or Refractory, Indolent Non-Hodgkin's Lymphoma Who Completed and Responded to Rituximab-based Immunochemotherapy Induction and Initial 2-year Rituximab Maintenance Therapy Administered Subcutaneously

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.

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Anticipated time on study treatment is until disease progression, unacceptable toxicity or end of study, whichever occurs first.

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Phase 3
Phase

NCT01461928 2010-023407-95 MO25455
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**#18 Years**	**No**

Inclusion Criteria:

- Histologically confirmed Cluster of Differentiation 20-positive (CD20+) follicular NHL Grade 1, 2 or 3a, or other CD20+ indolent NHL (Waldenström's macroglobulinemia or lymphoplasmacytic lymphoma, marginal zone lymphoma) according to World Health Organization (WHO) classification system
- Participants must have received and must have relapsed or been refractory to, one or more lines of adequate therapy prior to enrollment, including at least one line consisting of immunotherapy and/or chemotherapy and/or radiotherapy
- Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to (<=) 2

Exclusion Criteria:

- Transformation to high-grade lymphoma
- Aggressive lymphoma (for example, mantle cell lymphoma [MCL])
- Presence or history of central nervous system (CNS) lymphomatous disease
- Other malignancy within 5 years prior to enrollment, except for curatively treated carcinoma in situ of the cervix, squamous cell carcinoma of the skin or basal cell skin cancer, or cervical carcinoma Stage 1B or less, breast cancer in situ or localized prostate cancer Stage T1c if treated with curative intent and relapse- and metastasis-free for at least 2 years prior to enrollment
- Inadequate hematological, hepatic or renal function
- Known human immunodeficiency virus (HIV) infection
- Active and/or severe infection (e.g. tuberculosis, sepsis and opportunistic infections, active hepatitis B or C)
- Pregnant or breastfeeding women

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