KURZPROTOKOLL
PrefMab (MO28457)

Öffentlicher Titel	Subkutane oder intravenöse Verabreichung von Rituximab bei nicht-vorbehandeltem, CD20+ DLBCL oder follikulärem NHL
Wissenschaftl. Titel	Eine randomisierte, offene, multizentrische Studie zur Bewertung der Patientenpräferenz bei Vergleich der subkutanen und intravenösen Verabreichung von Rituximab bei nicht-vorbehandelten Patienten mit CD20+ diffus großzelligem BZell-Lymphom oder CD20+ follikulärem Non-Hodgkin-Lymphom Grad 1, 2 oder 3a.
Kurztitel	PrefMab (MO28457)
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - neu diagnostiziert / de novo
Ziele	- Proportion of patients indicating an overall preference via Patient Preference Questionnaire (PPQ) for either the subcutaneous (SC) or intravenous (IV) administration of MabThera/Rituxan - Safety: Incidence of adverse events - Administration time SC vs IV - Patient assessed satisfaction SC vs IV: Cancer Therapy Satisfaction Questionnaire (CTSQ)/Rituximab Administration Satisfaction Questionnaire (RASQ) - Complete response (CR) rate including complete response unconfirmed (CRu) 4-8 weeks after last dose of induction treatment - Event-free survival (EFS) - Disease-free survival (DFS) - Progression-free survival (PFS) - Overall survival (OS) - Immunogenicity: Anti-rituximab and anti-human recombinant hyaluronidase [rHuPH20] antibodies, associated rituximab concentration level)
Einschlusskriterien	- Adult patients, >/= 18 and </= 80 years of age - Histologically confirmed, previously untreated CD20+ diffuse large B-cell lymphoma (DLBCL) or CD20+ follicular non-Hodgkin's lymphoma (NHL) Grade 1, 2, or 3a, according to WHO classification - An International Prognostic Index (IPI) score of 1-4 or IPI score of 0 with bulky disease, defined as one lesion >/= 7.5 cm, or Follicular Lymphoma International Prognostic Index (FLIPI; low, intermediate or high risk) - At least one bi-dimensionally measurable lesion defined as >/=1.5 cm in its largest dimension on CT scan - Eastern Cooperative Oncology Group (ECOG) performance status </= 3
Ausschlusskriterien	- Transformed lymphoma or follicular lymphoma IIIB - Primary central nervous system (CNS) lymphoma, blastic variant of mantle-cell lymphoma, histologic evidence of transformation to Burkitt lymphoma, primary mediastinal DLBCL, primary effusion lymphoma, primary cutaneous DLBCL, or primary DLBCL of the testis - History of other malignancy that could affect compliance with the protocol or interpretation of the results; this includes a malignancy that has been treated but not with curative intent, unless the malignancy has been in remission for >/= 5 years prior to enrolment; patients with a history of curatively treated basal or squamous cell carcinoma or melanoma of the skin or in situ carcinoma of the cervix are eligible - Prior therapy for DLBCL or NHL, with the exception of nodal biopsy or local irradiation

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	- Prior treatment with cytotoxic drugs (with the exclusion of methotrexate for CNS prophylaxis in DLBCL) or rituximab for another condition, or prior use of an anti-CD20 drug - Prior use of monoclonal antibody within 3 months prior to randomization - Chemotherapy or other investigational therapy within 28 days prior to randomization - Ongoing corticosteroid use > 30 mg/day prednisolone or equivalent - Inadequate renal. hematologic or hepatic function - Active and/or severe infection or any major episode of infection within 4 weeks prior to randomization - Active hepatitis B virus or active hepatitis C virus infection - History of human immunodeficiency (HIV) seropositive status - A positive pregnancy test in women of childbearing potential - Life expectancy of less than 6 months
Alter	18 - 80 Jahre
Molekularer Marker	CD20
Fallzahl	900
Sponsor	Hoffmann-La Roche (Hauptsponsor)
Förderer	Hoffmann-La Roche
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01724021 EudraCT 2012-003230-17

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