KURZPROTOKOLL
GAZAI

Öffentlicher Titel	Phase II Studie zu Obinutuzumab bei follikulärem Lymphom in der frühen Phase
Wissenschaftl. Titel	Therapy of Nodal Follicular Lymphoma (WHO Grade 1/2) in Clinical Stage I/II Using Response Adapted Involved Site Radiotherapy in Combination With Gazyvaro
Kurztitel	GAZAI
Studienart	multizentrisch, Therapiestudie, offen/unverblindet, einarmig
Studienphase	Phase II
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - neu diagnostiziert / de novo
Einschlusskriterien	- Centrally reviewed CD20-positive follicular lymphoma grade 1/2 based on WHO classification (2016) - Untreated (radiation-, chemo- or immunotherapy) nodal lymphoma (including involvement of Waldeyer´s ring) - ECOG: 0-2 - Stage: clinical stage I or II (Ann Arbor classification) - Risk profile: Largest diameter of the lymphoma * 7 cm (sectional images) - Written informed consent and willingness to cooperate during the course of the trial - Adequate hematologic function (unless abnormalities are related to NHL), defined as follows: Hemoglobin 9.0 g/dL; absolute neutrophil count 1.5 × 109/L, Platelet count 75 × 109/L - Capability to understand the intention and the consequences of the clinical trial - Adequate contraception for men and women of child-bearing age during therapy and 18 months thereafter - Patients with non-active hepatitis B infection (HBsAg neg/HBcAB pos/HBV DNA neg) under 1-year require prophylactic anti-viral therapy (e.g. Entecavir®) possible (see also 5.6. Prior and Concomitant Disease)
Ausschlusskriterien	- Extra nodal manifestation - Secondary cancer in the patient's medical history (exclusion: basalioma, spinalioma, melanoma in situ, bladder cancer T1a, non-metastasized solid tumor in constant remission, which was diagnosed >3 years ago - Concomitant diseases: congenital or acquired immune-deficiency syndromes, active infections including viral hepatitis (serology positive for HBsAg or HBcAb in combination positive HBV DNA), uncontrolled concomitant diseases including significant cardiovascular or pulmonary disease (see also 5.6. Prior and Concomitant Disease) - Severe psychiatric disease - Pregnancy / lactation - Known hypersensitivity against Gazyvaro (Obinutuzumab) or drugs with similar chemical structure or any other additive of the pharmaceutical formula of the study drug - Participation in another interventional trial or follow-up period of a competing trial which can influence the results of this current trial - Creatinine > 1.5 times the upper limit of normal (ULN) (unless creatinine clearance normal), or calculated creatinine clearance < 40 mL/min - AST or ALT > 2.5 × ULN - Total bilirubin >= 1.5 × ULN - INR > 1.5 × ULN - PTT or aPTT > 1.5 × the ULN
Alter	18 Jahre und älter

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Sponsor	Universität Heidelberg (Hauptsponsor)
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03341520 EudraCT 2016-002059-89 (primäres Register)
Links	Studiendokumente zum Download (roXtra)