

KURZPROTOKOLL **NHL 7-2008**

Öffentlicher Titel	Bedeutung der Dauer der Erhaltungstherapie mit Rituximab bei niedrig-malignen NHL (MAINTAIN)
Wissenschaftl. Titel	Prospective Randomized Multicenter Study in First-line Treatment of Advanced progredleNT Follicular And Other IndoleNt and Mantle Cell Lymphomas
Kurztitel	NHL 7-2008
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II/III
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), niedrig-maligne: andere NHL - neu diagnostiziert / de novo
Ziele	<ul style="list-style-type: none">- PFS- Remission rate and duration; event free-, progression free-, disease free- and over all survival
Einschlusskriterien	<ul style="list-style-type: none">- Patients with histological verified CD20-positive B-Cell-Lymphoma of the following entities:<ul style="list-style-type: none">- - Follicular Lymphoma Grade 1 and 2- - Lymphoplasmocytic lymphoma / Immunocytoma (Morbus Waldenström) and small cell lymphocytic lymphoma (CLL without leukemic hemogram)- - Marginal zone lymphoma, nodal and extra nodal- - Mantle cell lymphoma- No prior therapy with cytotoxics, interferon or monoclonal antibodies- Need for therapy, except mantle cell lymphomas- Stadium III or IV or Stadium with II bulky disease (> 7 cm diameter, or 3 lesions > 5 cm)- General condition WHO 0-2- Age min. 18 years, max. 80 years- Negative pregnancy test, contraceptives mandatory for women of child-bearing age- Actual histology, not older than 6 months required- Written informed consent
Ausschlusskriterien	<ul style="list-style-type: none">- Patients not meeting the inclusion criteria above- Possibility of a primary radiation therapy with curative intention- Pretreatment, except a single, localized radiation therapy (radiation field not larger than 2 adjacent lymph node regions)- Co-morbidities, excluding a therapy according to the protocol:<ul style="list-style-type: none">- - severe, medicinal not adjustable hypertension- - severe limited capacity of the heart (NYHA III or IV), the lung (WHO-Grade III or IV), the liver and kidneys (creatinin > 2 mg/dl, GOT and GPT or bilirubin 3 x ULN), except if caused by lymphoma- - severe, medicinal not adjustable diabetes mellitus- - active autoimmune disease- - active infection, requiring antibiotic therapy- Patients with proven HIV-infection- Active replicating hepatitis-Infection- Severe psychiatric diseases- Lacking or anticipated non-compliance- Known hypersensitivity against the active components or additives or mouse-proteins

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- Pregnant or nursing women
- Patients with a secondary malignancy or malignant disease in his history if, curative surgery can not be doubtless assured

Alter

18 Jahre und älter

**Registrierung in anderen
Studienregistern**

EudraCT 2008-005859-16
ClinicalTrials.gov NCT00877214 (primäres Register)

Therapie

Rituximab, Observation