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 progredIeNT 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	- PFS - Remission rate and duration; event free-, progression free-, disease free- and over all survival
Einschlusskriterien	- Patients with histological verified CD20-positive B-Cell-Lymphoma of the following entities: - - 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	- 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: - - 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

	- 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