

**KURZPROTOKOLL**  
**NHL 7-2008**

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

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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