KURZPROTOKOLL
Optimal (> 60 Jahre)

Öffentlicher Titel	Studie zur Verbesserung der Therapieergebnisse bei älteren Patienten mit CD20+ DLBCL
Wissenschaftl. Titel	Improvement of Outcome and Reduction of Toxicity in Elderly Patients With CD20 DLBCL by an Optimised Schedule of Rituximab, Substitution of Conventional by Liposomal Vincristine, and FDG-PET Based Reduction of Therapy.
Kurztitel	Optimal (> 60 Jahre)
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: Neu diagnostiziert / de novo
Ziele	- "OPTIMAL>60 Less Favourable" Patients with less favourable prognosis: - To test whether progression-free survival (PFS) can be improved by substituting conventional by liposomal vincristine; - To test whether PFS can be improved by 12 optimised applications instead of 8 bi-weekly applications of rituximab. - "OPTIMAL>60 Favourable": Patients with favourable prognosis: - Comparison of neurotoxicity of conventional and lipsosomal vincristine; - Determination of progression-free survival (PFS) outcome for the treatment strategy of reducing treatment in patients with negative FDG-PET after 4 x R-CHOP/CHLIP-14 - "OPTIMAL>60 Favourable" and "OPTIMAL>60 Less Favourable": - Estimation of the prognostic effect of FDG-PET after induction therapy on treatment outcome - Estimation of the vincristine related neurotoxicity (“OPTIMAL>60 Less Favourable only) and other toxicities (all patients).
Einschlusskriterien	- 1. All risk groups (IPI 1-5) - 2. Diagnosis of aggressive CD20+. - 3. B-NHL: - a. Foll. lymphoma grade IIIb - b. DLBCL, not otherwise specified (NOS) - i. common morphologic variants: - ii. centroblastic - ii. immunoblastic - ii. anaplastic - i. rare morphologic variants - c. DLBCL subtypes/entities: - i. T-cell/histiocyte-rich large B-cell lymphoma (LBCL) - i. primary cutaneous DLBCL, leg type - i. EBV-pos. DLBCL of the elderly - d. DLBCL associated with chronic inflammation - e. primary mediastinal (thymic) LBCL - f. intravascular LBCL - g. ALK-positive LBCL - h. plasmoblastic lymphoma - j. primary effusion lymphoma - k. B-cell lymphoma, unclassifiable, with features intermediate between DLBCL and Burkitt lymphoma

- l. B-cell lymphoma, unclassifiable, with features intermediate between DLCBL and Hodgkin lymphoma
- 4. Performance status: ECOG 0-2 after prephase treatment (PT). The performance status of each patient must be assessed before the initiation and after the end of PT. The PT status must be documented in the Staging CRF; the performance status after the PT must also be documented in the respective PT CRF.
- 5. Written informed consent of the patient
- 6. Contract of participation signed by the study centre and sponsor

Ausschlusskriterien

- Already initiated lymphoma therapy (except for the PT cf. 8.7.2)
- Serious accompanying disorder or impaired organ function (except when due to lymphoma involvement), in particular:
- a. heart: angina pectoris CCS>2, cardiac failure e.g. NYHA>2 and/or EF<50% or FS<25% in nuclear medicine examination/echocardiography
- b. lungs: if respiratory problems are suspected the patient is to be excluded if the resultant pulmonary function test shows FeV1<50% or a diffusion capacity<50% of the reference values
- c. kidneys: creatinine>2 times the upper reference limit
- d. liver: bilirubin>2 times the upper reference limit, aspartate transaminase (AST, SGOT) or alanine transaminase (ALT, SGPT) >3 x institutional upper reference limit
- e. uncontrollable diabetes mellitus (PT with prednisone/prednisolone!)
- Platelets <100 000/mm³, leukocytes <2500/mm³ (if not due to lymphoma)
- Known hypersensitivity to the medications to be used
- Known HIV-positivity
- Patients with severe impairment of immune defense
- Patients with constipation with imminent risk of ileus
- Chronic active hepatitis
- Poor patient compliance
- Simultaneous participation in other treatment studies or in another clinical trial within the last 6 months
- Prior chemo- or radiotherapy, long-term use of corticosteroids or anti- neoplastic drugs for previous disorder
- Other concomitant tumour disease and/or tumour disease in the past 5 years (except basalioma of the skin and carcinoma in situ)
- CNS involvement of lymphoma (intracerebral, meningeal, intraspinal) or primary CNS lymphoma
- Persistent neuropathy grade >=2 (NCI CTC-AE v4.03)
- History of persistent active neurologic disorders grade >2 including demyelinating form of Charcot-Marie-Tooth syndrome, acquired demyelinating disorders, or other demyelinating condition
- Pregnancy or breast-feeding women
- Active serious infections not controlled by oral and/or intravenous antibiotics or anti-fungal medication Any medical condition which in the opinion of the investigator places the subject at an unacceptably high risk for toxicities.
- MALT lymphoma
- Non-conformity to eligibility criteria
- Persons not able to understand the impact, nature, risks and consequences of the trial (including language barrier)

	- Persons not agreeing to the transmission of their pseudonymous data Persons depending on sponsor or investigator - Persons from highly protected groups. Pts. with CNS lymphoma should not be included in this study.
Alter	61 - 80 Jahre
Molekularer Marker	CD20
Fallzahl	1152
Sponsor	Universitätsklinikum Saarland (Hauptsponsor)
Förderer	Universitätsklinikum Saarland
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01478542 (primäres Register) EudraCT 2010-019587-36
Therapie	Drug: Conventional Vincristine; Drug: Liposomal Vincristine
Links	Studiendokumente zum Download (roXtra)