

KURZPROTOKOLL **MATRix**

Öffentlicher Titel	Phase III Studie zu hochdosierter Chemotherapie und Autologer SZT versus konventioneller Chemotherapie bei primären ZNS Lymphomen
Wissenschaftl. Titel	High-dose chemotherapy and autologous stem cell transplant or consolidating conventional chemotherapy in primary CNS lymphoma - randomized phase III trial
Kurztitel	MATRix
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarstig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: Neu diagnostiziert / de novo
Ziele	- To demonstrate the efficacy measured as progression-free survival (PFS) of intensive chemotherapy followed by autologous stem-cell transplantation compared to conventional chemotherapy - To compare high-dose chemotherapy followed by autologous stem cell transplantation with optimized conventional chemotherapy regarding OS, treatment response and treatment related morbidities (neurotoxicity and adverse events) in patients with primary CNS lymphoma.
Einschlusskriterien	- 1. Immunocompetent patients with newly-diagnosed primary central nervous system B-cell lymphoma - 2. Age 18-65 years irrespective of ECOG or 66-70 years (with ECOG Performance Status 2) - 3. Histologically or cytologically assessed diagnosis of B-cell lymphoma by local pathologist. Diagnostic sample obtained by stereotactic or surgical biopsy, CSF cytology examination or vitrectomy - 4. Disease exclusively located in the CNS - 5. At least one measurable lesion - 6. Previously untreated patients (previous or ongoing steroid treatment admitted) - 7. Sexually active patients of childbearing potential who agree to take adequate contraceptive measures during study participation - 8. Written informed consent obtained according to international guidelines and local laws by patient or authorized legal representative in case patient is temporarily legally not competent due to his or her disease - ADDITIONAL RANDOMIZATION CRITERIA - 1. Sufficient stem cell harvest (5×10^6 CD34+ cells/kg of body weight) - 2. Complete remission, unconfirmed complete remission or partial remission - 3. Central pathology results confirming local results
Ausschlusskriterien	- 1. Congenital or acquired immunodeficiency - 2. Systemic lymphoma manifestation (outside the CNS) - 3. Isolated ocular lymphoma without manifestation in the brain parenchyma or spinal cord - 4. Previous or concurrent malignancies with the exception of surgically cured carcinoma in-situ of the cervix, carcinoma of the skin or other kinds of cancer without evidence of disease for at least 5 years - 5. Previous Non-Hodgkin lymphoma at any time - 6. Inadequate bone marrow (platelet count decreased $\geq$ CTC grade 1, anemia $\geq$ CTC grade 1, neutrophil count decreased $\geq$ CTC grade 1), renal (creatinine clearance <60 ml/min), cardiac (ejection fraction decreased $\geq$ CTC grade 2), or hepatic function (blood bilirubin increased $\geq$ CTC grade 2, alanine aminotransferase increased $\geq$ CTC grade 2, aspartate aminotransferase increased $\geq$ CTC grade 2 or gamma-GT increased $\geq$ CTC grade 2)

KURZPROTOKOLL MATRix

- 7. HBsAg, anti-HBc and HCV positivity
- 8. HIV infection, previous organ transplantation or other clinical evident form of immunodeficiency
- 9. Concurrent treatment with other experimental drugs or participation in a clinical trial within the last thirty days before the start of this study
- 10. Symptomatic coronary artery disease, cardiac arrhythmias uncontrolled with medication or myocardial infarction within the last 6 months (New York Heart Association Class III or IV heart disease)
- 11. Severe non-compensated pulmonary disease (IVC <55%, DLCO <40%)
- 12. Third space fluid accumulation >500 ml
- 13. Hypersensitivity to study treatment or any component of the formulation
- 14. Taking any medications likely to cause interactions with the study medication
- 15. Known or persistent abuse of medication, drugs or alcohol
- 16. Patient without legal capacity and who is unable to understand the nature, significance and consequences of the study and without designated legal representative
- 17. Persons who are in a relationship of dependency/employment to the sponsor and/ or investigator
- 18. Any familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule
- 19. Concurrent (or planned) pregnancy or lactation
- 20. Fertile patients refusing to use safe contraceptive methods during the study

Alter 18 - 70 Jahre

Fallzahl 250

Prüfzentren **Innere Medizin 2** (Nachbeobachtung)
Hämatologie / Medizinische Onkologie
Theodor-Stern-Kai 7
60590 Frankfurt am Main
Annerose Kopalla
Tel: 069 6301-7969
Fax: 069 6301-7373
annerose.kopalla@unimedizin-ffm.de

Sponsor Klinikum Stuttgart

Förderer Bundesministerium für Bildung und Forschung

Registrierung in anderen Studienregistern EudraCT 2012-000620-17
Deutsches Register Klinischer Studien DRKS00005503

Therapie In the presently planned multicentre Phase III trial the two therapies will be compared: Patients will be randomized after intensified induction treatment with 4 cycles rituximab, methotrexate, cytarabine and thiotepa (MATRix) between first-line high-dose chemotherapy against conventional consolidating therapy with 2 cycles of conventional chemotherapy with R-DeVIC (Rituximab, Dexamthason, Etoposide, Ifosfamide, Carboplatin).