

KURZPROTOKOLL **MCL R2 Elderly**

Öffentlicher Titel	Phase III Studie zur alternierenden Immunochemotherapie bestehend aus R-CHOP + R-HAD vs R-CHOP allein, gefolgt von Lenalidomid mit Rituximab vs Rituximab allein bei älteren Patienten mit Mantelzelllymphom
Wissenschaftl. Titel	Efficacy of alternating immunochemotherapy consisting of R-CHOP + R-HAD versus R-CHOP alone, followed by maintenance therapy consisting of additional lenalidomide with rituximab versus rituximab alone for older patients with mantle cell lymphoma
Kurztitel	MCL R2 Elderly
Studienart	multizentrisch, randomisiert, offen/unverblindet, mehrarmig
Studienphase	Phase III
Erkrankung	Blut: Non-Hodgkin-Lymphome (NHL), hoch-maligne: Neu diagnostiziert / de novo
Einschlusskriterien	<ul style="list-style-type: none">- signed informed consent form- Biopsy-proven mantle cell lymphoma according to WHO classification, including evidence of cyclin D1 overexpression or the translocation t(11;14)(q13;q32),- ≥ 60 years of age and ineligible for autologous transplant- Ann Arbor stage II-IV- previously untreated (except for patients randomized directly for maintenance treatment who will receive 8 RCHOP before registration in the trial)- ECOG performance status ≤ 2- Male subjects must: (a) agree to use a condom during sexual contact with a woman of childbearing potential, even if they have had a vasectomy, throughout lenalidomide therapy; (b) agree to not donate semen during lenalidomide therapy- All subjects must: (a) have an understanding that the lenalidomide could have a potential teratogenic risk; (b) agree to abstain from donating blood while taking lenalidomide therapy; (c) agree not to share study medication with another person; (d) be counselled about pregnancy precautions and risks of foetal exposure- Additional inclusion criteria for randomization in maintenance phase : (a) CR, CRu or PR after induction treatment, determined as per Cheson 1999 criteria by investigator; (b) During the run-in period of 6 months starting from the date of the first patient randomized in the trial: in case of direct randomization into maintenance phase, patient must have been treated in first line by 6-8 cycles of R-CHOP
Ausschlusskriterien	<ul style="list-style-type: none">- Female of child-bearing potential (without natural menopause for at least 24 consecutive months, a hysterectomy or bilateral oophorectomy)- Any of the following laboratory abnormalities, if not related to lymphoma: (a) Absolute neutrophils count (ANC) $< 1,000 / \text{mm}^3$ ($1.0 \times 10^9 / \text{L}$) if not result of a BM infiltration; (b) Platelet counts $< 75,000 / \text{mm}^3$ ($75 \times 10^9 / \text{L}$) if not result of a BM infiltration; (c) Serum aspartate transaminase (AST/SGOT) or alanine transaminase (ALT/SGPT) $> 3.0 \times$ upper limit of normal (ULN); (d) Serum total bilirubin > 1.5 ULN (except if due to Gilbert's syndrome)- Calculated creatinine clearance (Cockcroft-Gault formula or MDRD) $< 30 \text{ mL} / \text{min}$- Central nervous system involvement by lymphoma- Contraindication for medicamentous DVT prophylaxis for patients at high risk for DVT- Prior history of malignancies other than MCL unless the subject has been free of the disease for ≥ 5 years (Exceptions: Basal or squamous cell carcinoma of the skin, Carcinoma in situ of the cervix or of the breast, Incidental histologic finding of prostate cancer (TNM stage of T1a or T1b))- Any serious medical condition, laboratory abnormality, or psychiatric illness that would prevent the patient to receive the study medication as planned.- Poor cardiac function (LVEF $< 50\%$) on echocardiography

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- Seropositivity for human immunodeficiency virus (HIV, mandatory test) Seropositivity for hepatitis C virus (HCV, mandatory test), Active viral infection with hepatitis B virus (HBV, mandatory test): (a) HBsAg positive; (b) HBsAg negative, anti-HBs positive and anti-HBc positive
- Uncontrolled illness including, but not limited to: (a) Active infection requiring parenteral antibiotics; (b) Uncontrolled diabetes mellitus; (c) Chronic symptomatic congestive heart failure (Class NYHA III or IV); (d) Unstable angina pectoris, angioplasty, stenting, or myocardial infarction within 6 months; (e) Clinically significant cardiac arrhythmia that is symptomatic or requires treatment, or asymptomatic sustained ventricular tachycardia
- Prior \geq Grade 3 allergic hypersensitivity to thalidomide
- Prior \geq Grade 3 rash or any desquamating (blistering) rash while taking thalidomide
- Subjects with \geq Grade 2 neuropathy
- Known anti-murine antibody (HAMA) reactivity or known hypersensitivity to murine antibodies
- Prior use of lenalidomide
- Participation in another clinical trial within three weeks before randomization in this study
- Additional exclusion criteria for randomization in maintenance phase: (a) SD or PD after induction treatment determined as per Cheson 1999 criteria assessed by investigator; (b) Patients who had not received at least 6 cycles of R-CHOP21 or 2 cycles of R-CHOP21 / 2 cycles of R-HAD28 (alternating); (c) Patients with serious underlying medical conditions, which could impair the ability to receive maintenance treatment; (d) Calculated creatinine clearance (Cockcroft-Gault formula or MDRD) of < 30 mL/min at screening for maintenance; (e) ANC $< 1,000$ cells/mm³ (1.0×10^9 /L) at screening for maintenance; (f)
- Platelet count $< 50,000$ cells/mm³ (50×10^9 /L) at screening for maintenance.

Alter	18 Jahre und älter
Fallzahl	633
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Sponsor	LYSARC
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