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	- 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	- 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 /mm3 (1.0 x 109/L) if not result of a BM infiltration; (b) Platelet counts < 75,000/mm3 (75 x 109/L) if not result of a BM infiltration; (c) Serum aspartate transaminase (AST/SGOT) or alanine transaminase (ALT/SGPT) >3.0 x 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 mL /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

	- 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 >= Grade 3 allergic hypersensitivity to thalidomide - Prior >= Grade 3 rash or any desquamating (blistering) rash while taking thalidomide - Subjects with >= 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/mm^3 (1.0 X 109/L) at screening for maintenance; (f) - Platelet count < 50,000 cells/mm^3 (50 X 109/L) at screening for maintenance.
Alter	18 Jahre und älter
Fallzahl	633
Sponsor	LYSARC
Registrierung in anderen Studienregistern	EudraCT 2012-002542-20