KURZPROTOKOLL
HD 6

Öffentlicher Titel	Randomisierte Phase III Studie mit Elotuzumab bei neu diagnostiziertem Multiplen Myelom
Wissenschaftl. Titel	A Randomized Phase III Trial on the Effect of Elotuzumab in VRD Induction /Consolidation and Lenalidomide Maintenance in Patients With Newly Diagnosed Myeloma
Kurztitel	HD 6
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, mehrarmig
Studienphase	Phase III
Erkrankung	Blut: Multiples Myelom: neu diagnostiziert / de novo
Einschlusskriterien	- Confirmed diagnosis of untreated multiple myeloma requiring systemic therapy (diagnostic criteria (IMWG updated criteria (2014)1) see appendix I. For some patients systemic therapy may be required though these diagnostic criteria are not fulfilled. In this case the GMMG study office has to be consulted prior to inclusion.) - Measurable disease, defined as any quantifiable monoclonal protein value, defined by at least one of the following three measurements:(a) Serum M-protein >= 10g/l (for IgA >= 5g/l); (b) Urine light-chain (M-protein) of >= 200 mg/24 hours; (c) Serum FLC assay: involved FLC level 10 mg/dl provided sFLC ratio is abnormal - Age 18 - 70 years inclusive - WHO performance status 0-3 (WHO=3 is allowed only if caused by MM and not by co -morbid conditions) (see appendix III) - Negative pregnancy test at inclusion (women of childbearing potential) - For all men and women of childbearing potential: patients must be willing and capable to use adequate contraception during the complete therapy. Patients must agree on the requirements regarding the lenalidomide pregnancy prevention programme described in chapter 6. - All patients must: (a) agree to abstain from donating blood while taking lenalidomide and for 28 days following discontinuation of lenalidomide therapy; (b) agree not to share study drug lenalidomide with another person and to return all unused study drug to the investigator or pharmacist - Ability of patient to understand character and individual consequences of the clinical trial - Written informed consent (must be available before enrollment in the trial)
Ausschlusskriterien	- - Patient has known hypersensitivity to any drugs given in the protocol, notably bortezomib, lenalidomide, dexamethasone and elotuzumab or to any of the constituent compounds (incl. boron and mannitol). - Systemic AL amyloidosis (except for AL amyloidosis of the skin or the bone marrow) - Previous chemotherapy or radiotherapy during the past 5 years except local radiotherapy in case of local myeloma progression. (Note: patients may have received a cumulative dose of up to 160 mg of dexamethasone or equivalent as emergency therapy within 4 weeks prior to study entry.) - Severe cardiac dysfunction (NYHA classification III-IV, see appendix IIIB) - Significant hepatic dysfunction (serum bilirubin >= 1,8mg/dl and/or ASAT and/or ALAT >= 2.5 times normal level), unless related to myeloma. (Note: if the mentioned limits for bilirubin or ASAT/ALAT are exceeded, but there is no significant hepatic dysfunction at investigator’s discretion, the GMMG study office has to be consulted prior to inclusion) - Patients with renal insufficiency requiring hemodialysis - HIV positivity - Patients with active or history of hepatitis B or C - Patients with active, uncontrolled infections

- Patients with peripheral neuropathy or neuropathic pain, CTC grade 2 or higher (as defined by the NCI Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 4.0, see appendix V)
- Patients with a history of active malignancy during the past 5 years with the exception of basal cell carcinoma of the skin or stage 0 cervical carcinoma treated with curative intent
- Patients with acute diffuse infiltrative pulmonary and/or pericardial disease
- Autoimmune hemolytic anemia with positive Coombs test or immune thrombocytopenia
- Platelet count < 75 x 109/l, or, dependent on bone marrow infiltration by plasma cells, platelet count < 30 x 109/l (patients with platelet count < 75 x 109/l, but > 30 x 109/l may be eligible if percentage of plasma cells in bone marrow is >= 50%), (transfusion support within 14 days before the test is not allowed)
- Haemoglobin< 8.0 g/dl, unless related to myeloma
- Absolute neutrophil count (ANC) < 1.0 x 109/l (the use of colony stimulating factors within 14 days before the test is not allowed), unless related to myeloma
- Pregnancy and lactation
- Participation in other clinical trials. This does not include long-term follow-up periods without active drug treatment of previous studies during the last 6 months.
- No patient will be allowed to enrol in this trial more than once.

Alter	18 - 70 Jahre
Fallzahl	516
Prüfzentren	**Innere Medizin 2** (Geschlossen) Hämatologie / Medizinische Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Allg. Ansprechpartner der Abteilung Häma/Onko
Sponsor	Universitätsklinikum Heidelberg
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02495922 EudraCT 2014-003079-40