KURZPROTOKOLL
GMMG HD7

Öffentlicher Titel	Phase III Studie zu Isatuximab beim neu diagnostizierten Multiplen Myelom
Wissenschaftl. Titel	A randomized phase III trial assessing the benefit of the addition of isatuximab to lenalidomide / bortezomib / dexamethasone (RVd) induction and lenalidomide maintenance in patients with newly diagnosed multiple myeloma
Kurztitel	GMMG HD7
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
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 IA. 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.) - Patient is eligible for high dose therapy and autologous stem cell transplantation. - Measurable disease, defined as any quantifiable monoclonal protein value, defined by at least one of the following three measurements: - -> Serum M-protein >= 10g/l (for IgA >= 5g/l) - -> Urine light-chain (M-protein) of >= 200 mg/24 hours - -> Serum FLC assay: involved FLC level >= 10 mg/dl provided sFLC ratio is abnormal - Age 18 - 70 years inclusive - WHO performance status 0-2 - Negative pregnancy test at inclusion (females of childbearing potential) - All patients must agree on the requirements regarding the lenalidomide pregnancy prevention plan described in section 6. For all men and females of childbearing potential: patients must be willing and capable to use adequate contraception during the complete therapy. - All patients must agree to abstain from donating blood while taking lenalidomide and for 28 days following discontinuation of lenalidomide therapy - All patients must 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 - Provide written informed consent (must be available before enrolment in the trial)
Ausschlusskriterien	- Patient has known hypersensitivity (or contraindication) to dexamethasone, sucrose histidine (as base and hydrochloride salt), boron, mannitol, and polysorbate 80 or any of the components of study therapy that are not amenable to premedication with steroids or H2 blockers that would prohibit further treatment with these agents - Systemic AL amyloidosis (except for AL amyloidosis of the skin or the bone marrow) - Plasma cell leukemia - 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.) Previous therapy due to smouldering myeloma may be acceptable. In this case the GMMG study office has to be consulted prior to inclusion - Severe cardiac dysfunction (NYHA classification III-IV), ejection fraction < 40% - Significant hepatic dysfunction (ASAT and/or ALAT >= 3 times normal level and/or serum bilirubin >= 1.5 times normal level if not due to hereditary abnormalities as Gilbert's disease), unless related to myeloma.

- Patients with active or history of hepatitis B or C
- HIV positivity
- Patients with active, uncontrolled infections
- Patients with severe renal insufficiency (Creatinine Clearance < 30ml/min)
- 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 5.0)
- Patients with a history of active malignancy during the past 5 years with the exception of following malignancies after curative therapy: basal cell carcinoma of the skin, squamous cell skin carcinoma, stage 0 cervical carcinoma or any in situ malignancy
- Patients with acute diffuse infiltrative pulmonary and/or pericardial disease
- Autoimmune hemolytic anemia with positive Coombs test or immune thrombocytopenia
- Platelet count < 75 x 10^9/l
- Haemoglobin < 8.0 g/dl, unless related to myeloma
- Absolute neutrophil count (ANC) < 1.0 x 10^9/l (the use of colony stimulating factors within 14 days before the test is not allowed)
- Corrected serum calcium > 14 mg/dl (> 3.5 mmol/l)
- Unable or unwilling to undergo thromboprophylaxis
- 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.
- Prisoners or subjects who are legally institutionalized, or those unwilling or unable to comply with scheduled visits, drug administration plan, laboratory tests, other study procedures, and study restrictions.
- No patients will be allowed to enrol in this trial more than once.

Alter

18 - 70 Jahre

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Sponsor	Universität Heidelberg
Registrierung in anderen Studienregistern	EudraCT 2017-004768-37 ClinicalTrials.gov NCT03617731 (primäres Register)
Links	Studiendokumente zum Download (roXtra)