KURZPROTOKOLL
DSMM XVII

Öffentlicher Titel	Phase III Studie zu Elotuzumab bei neu diagnostiziertem Multiplen Myelom und autologer Stammzelltransplantation
Wissenschaftl. Titel	Elotuzumab (E), in Kombination mit Carfilzomib, Lenalidomid und Dexamethason (E-KRd) gegen KRd vor und nach autologer Stammzelltransplantation bei neu diagnostiziertem Multiplen Myelom und mit nachfolgender Erhaltungstherapie mit Elotuzumab und Lenalidomid gegen Lenalidomid Monotherapie. Eine Phase III Studie der Deutschen Studiengruppe Multiples Myelom
Kurztitel	DSMM XVII
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Blut: Multiples Myelom: neu diagnostiziert / de novo
Einschlusskriterien	- Eligible for autologous stem cell transplantation (ASCT) - Patient must not have been previously treated with any prior systemic therapy for the treatment of multiple myeloma (only dexamethasone at a cumulative dose of 320 mg; plasmapheresis/dialysis without concomitant chemotherapy,local irradiation of bone lesions; and surgical intervention permitted as pretreatment) - Newly diagnosed multiple myeloma according to the IMWG updated criteria: Clonal bone marrow plasma cells >= 10% or biopsy proven bony or extramedullary plasmacytoma and any one or more of the following myeloma defining events: Evidence of end organ damage that can be attributed to the underlying plasma cell proliferative disorder, specifically: Hypercalcaemia: serum calcium > 0.25 mmol/L (> 1 mg/dL) higher than the upper limit of normal or > 2.75 mmol/L (> 11 mg/dL) Renal insufficiency: creatinine clearance < 40 mL per min or serum creatinine > 177 mol/L (> 2 mg/dL) Anaemia: haemoglobin value of > 2 g/dL below the lower limit of normal, or a haemoglobin value < 10 g/dL Bone lesions: one or more osteolytic lesions on skeletal radiography,computed tomography (CT), or PET-CT - Any one or more of the following markers of malignancy: Clonal bone marrow plasma cell percentage >= 60% Involved: uninvolved serum free light chain ratio >= 100, provided the absolute level of the involved light chain is at least 100 mg/L One or more focal lesions of at least 5mm or greater in size on MRI studies - Measurable disease parameters as follows: Serum monoclonal paraprotein (M-component) level >= 1 g/dL and/or urine M-protein level >= 200 mg/24 hours or In case of IgA myeloma: Serum monoclonal paraprotein level >= 0.5 g/dL and/or urine M-protein level >= 200 mg/24 hours or For patients with no detectable M-component: Serum FLC Assay: Involved FLC level >= 10 mg/dL (>= 100 mg/L) provided serum FLC ratio is abnormal ECOG Performance Status <= 2 Laboratory test results within these ranges: White blood cell count >= 2 x 109/L Absolute neutrophil (ANC) count >= 1.0 x 109/L Platelet count >= 75 x 109/L Haemoglobin > 8 g/dL Calculated creatinine clearance (according to MDRD) >= 30 mL/minute Total bilirubin <= 1.5 x upper limit of normal (ULN) AST and ALT <= 2.5 x ULN Corrected serum calcium level < 3.5 mmol/L (< 14 mg/dL) - Patient's legal capacity to consent to study participation - Patients capable to understand the purposes and risks of the study, who are willing and able to participate in the study and from whom written and dated informed consent to participate in the study has been obtained - All females must acknowledge to have understood the hazards lenalidomide can cause to an unborn fetus and the necessary precautions associated with the use of lenalidomide. must use adequate contraception and agree to use two reliable forms of contraception simultaneously or to practice complete abstinence must agree to have medically supervised pregnancy tests on a regular basis must agree to abstain from breastfeeding while taking lenalidomide, carfilzomib and elotuzumab and for at least 28 days after the last dose of lenalidomide, carfilzomib, and elotuzumab

- Male subjects must practice complete abstinence or use a condom during sexual contact with a pregnant female or a female with child bearing potential while taking lenalidomide, carfilzomib, and elotuzumab. not donate semen or sperm
- All subjects must agree to abstain from donating blood while taking lenalidomide, during dose interruptions and for at least 28 days after the last dose of lenalidomide. agree never to give lenalidomide to another person. agree to return all unused lenalidomide capsules to the investigator (with exception of prescribed lenalidomide capsules) be aware that no more than a 28-day lenalidomide supply may be dispensed with each cycle of lenalidomide during induction and consolidation therapy and be prescribed during maintenance therapy

Ausschlusskriterien

- POEMS syndrome (polyneuropathy, organomegaly, endocrinopathy, monoclonal protein, and skin changes)
- Waldenström's macroglobulinemia or IgM myeloma
- Plasma cell leukemia (> 2.0 x 109/L circulating plasma cells by standard differential blood count)
- Pregnant, breast-feeding females, FCBPs and males who are unwilling to comply with the lenalidomide Pregnancy Prevention Risk Management Plan
- Patients with high cardiovascular risk, including but not limited to history of myocardial infarction or coronary stenting in the past 6 months; NYHA Class III or IV heart failure, uncontrolled angina, uncontrolled hypertension, severe uncontrolled arrhythmias
- Prior cerebral vascular accident (CVA) with persistent neurological deficit
- Active infection
- Known HIV-seropositivity, active or chronic hepatitis A, B, C or D-infection (including patients who are tested anti-HBC positive and/or HBsAg positive)
- Any other severe concomitant disease or disorder, including the presence of laboratory abnormalities, which places the subject at unacceptable risk or which could influence patient's ability to participate in the study and his/her safety during the study or interfere with interpretation of study results
- Greater or equal to Grade 2 peripheral neuropathy on clinical examination within 14 days before enrollment
- Major surgery within 4 weeks prior to randomization
- Any systemic anti-myeloma therapy within 4 weeks of randomization except a max. cumulative dose of 320 mg auf dexamethasone
- Any prior or concurrent malignancy other than multiple myeloma
- Exceptions include patients who have been disease-free for at least five years before study entry or patients with adequately treated and completely resected basal cell or squamous cell skin cancer, in situ cervical, breast or prostate cancer
- Known hypersensitivity to carfilzomib, lenalidomide, and elotuzumab or to any of the excipients of carfilzomib, lenalidomide, and elotuzumab or to any other component of any study drug formulation
- Participation in any other clinical trial or treatment with any experimental drug or other experimental therapy within 28 days before enrolment to the study or during study participation until the end of treatment visit

Alter

18 - 70 Jahre

Prüfzentren

Innere Medizin 2 (Rekrutierung beendet)
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Links	Studiendokumente zum Download (roXtra)