KURZPROTOKOLL
MAIA

Öffentlicher Titel	Phase III Studie zu Daratumumab in Kombination mit Lenalidomid und Dexamethason als Erstlinienbehandlung bei Patienten mit Multiplem Myelom, die für eine Hochdosis-Chemotherapie ungeeignet sind.
Wissenschaftl. Titel	A Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Subjects with Previously Untreated Multiple Myeloma who are Ineligible for High Dose Therapy Protocol 54767414MMY3008
Kurztitel	MAIA
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Multiples Myelom: neu diagnostiziert / de novo
Ziele	- The purpose of this study is to compare the efficacy of daratumumab in combination with lenalidomide and dexamethasone to that of lenalidomide and dexamethasone in terms of progression-free survival (PFS) in participants with newly diagnosed multiple myeloma (a blood cancer of plasma cells) who are not candidates for high dose chemotherapy (treatment of disease, usually cancer, by chemical agents) and autologous stem cell transplant (ASCT). - The secondary objectives are: - To evaluate clinical outcomes including: Time to disease progression (TTP) ; Stringent CR (sCR) rate ; CR rate ; PFS2 (defined as time from randomization to progression on the next line of therapy or death, whichever comes first) ; Time to next treatment ; Overall response rate (CR + partial response [PR] rate) ; Proportion of subjects who achieve very good partial response (VGPR) or better ; Duration of response ; Overall survival
Einschlusskriterien	- Participant must have documented multiple myeloma satisfying the CRAB (calcium elevation, renal insufficiency, anemia and bone abnormalities) criteria, monoclonal plasma cells in the bone marrow greater than or equal to (>=) 10 percent (%) or presence of a biopsy proven plasmacytoma and measurable disease as defined by any of the following: (a)immunoglobulin (Ig) G myeloma (serum monoclonal paraprotein [Mprotein] level >=1.0 gram/deciliter [g/dL] or urine Mprotein level >=200 milligram[mg]/24 hours[hrs] or (b) IgA, IgM, IgD, or IgE multiple myeloma (serum Mprotein level >=0.5 g/dL or urine Mprotein level >=200 mg/24 hrs) or (c) light chain multiple myeloma without measurable disease in serum or urine (serum immunoglobulin free light chain >=10 mg/dL and abnormal serum immunoglobulin kappa lambda free light chain ratio) - Participant must have an Eastern Cooperative Oncology Group (ECOG) performance status score of 0, 1, or 2 - Participants who are newly diagnosed and not considered for highdose chemotherapy due to: being age >=65 years or participants less than (<) 65 years with presence of important comorbid condition(s) likely to have a negative impact on tolerability of high dose chemotherapy with stem cell transplantation. Sponsor review and approval of participants below 65 years of age is required before randomization - Women of childbearing potential must commit to either abstain continuously from sexual intercourse or to use 2 methods of reliable birth control simultaneously as deemed appropriate by the Investigator. Contraception must begin 4 weeks prior to dosing and must continue for 4 months after the last dose of daratumumab - Man, who is sexually active with a woman of childbearing potential potential must agree to use a latex or synthetic condom, even if he had a successful vasectomy, must agree to use an adequate contraception method as deemed appropriate by the Investigator, and must also agree to not donate sperm during the study and for 4 weeks after last dose of lenalidomide and 4 months after last dose of daratumumab

Ausschlusskriterien	- Participant has a diagnosis of primary amyloidosis, monoclonal gammopathy of undetermined significance (presence of serum Mprotein <3 g/dL absence of lytic bone lesions, anemia, hypercalcemia, and renal insufficiency related to the Mprotein), or smoldering multiple myeloma (asymptomatic multiple myeloma with absence of related organ or tissue impairment end organ damage) - Participant has a diagnosis of Waldenström's disease, or other conditions in which IgM M protein is present in the absence of a clonal plasma cell infiltration with lytic bone lesions - Participant has a history of malignancy (other than multiple myeloma) within 5 years before the date of randomization (exceptions are squamous and basal cell carcinomas of the skin and carcinoma in situ of the cervix, or malignancy that in the opinion of the Investigator, with concurrence with the Sponsor's medical monitor, is considered cured with minimal risk of recurrence within 5 years) - Participant has prior or current systemic therapy or SCT for multiple myeloma, with the exception of an emergency use of a short course (equivalent of dexamethasone 40 mg/day for a maximum 4 days) of corticosteroids before treatment - Participant has had radiation therapy within 14 days of randomization - Participant has known chronic obstructive pulmonary disease (COPD) (defined as a forced expiratory volume in 1 second [FEV1] <50% of predicted normal), persistent asthma, or a history of asthma within the last 2 years (controlled intermittent asthma or controlled mild persistent asthma is allowed) - Participants with known or suspected COPD or asthma must have a FEV1 test during Screening - Participant is known to be seropositive for history of human immunodeficiency virus (HIV) or known to have active hepatitis B or hepatitis C
Alter	18 Jahre und älter
Fallzahl	730
Sponsor	Janssen Research & Development (Hauptsponsor)
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02252172 EudraCT 2014-002273-11