Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

HAMLET

Öffentlicher Titel	Haploider versus teilweise HLA-identischer nicht-verwandter Spender bei hämatologischen Neoplasien
Wissenschaftl. Titel	A randomized controlled trial comparing outcome after hematopoietic cell transplantation from a partially matched unrelated versus haploidentical donor
Kurztitel	HAMLET
Studiennummer KN/ELN	LN_NN_2019_649
Studiengruppe	NN
Studienart	multizentrisch, prospektiv, offen, zweiarmig
Studienphase	Phase II/III
Erkrankung	Stammzelltransplantation (SZT) - ALL Stammzelltransplantation (SZT) - AML Stammzelltransplantation (SZT) - MDS
Leukämiestadium	.
Einschlusskriterien	- Males and females aged >= 18 years old. - Eligible diagnoses are listed below: - -> AML with adverse risk genetic abnormalities (according to the ELN guidelines)1. - -> AML with intermediate genetic abnormalities (according to ELN guidelines) either in first complete remission, after relapse, or with chemotherapy-refractory disease - -> AML with favourable genetic abnormalities (according to ELN guidelines) after relapse or with chemotherapy-refractory disease, except APL - -> AML with undefined genetic risk classification after relapse or with chemotherapy-refractory disease - -> AML arising from myelodysplastic syndrome (MDS) or a myeloproliferative neoplasia, except if favourable genetic abnormalities (according to ELN guidelines) are present - -> Therapy-related myeloid neoplasia except if favorable genetic abnormalities (according to ELN guidelines) are present - -> MDS with high risk or very high risk disease (according to the IPSS-R score2) - -> First CR of high-risk ALL, defined by one or more of these: - a) Early or mature T-ALL (CD1a negative). - b) Pro B-ALL with t(4v;11); KMT2A-rearrangements - c) Presence of BCR-ABL and/or t(9;22). - d) Persistence of minimal residual disease after the second induction course. - -> ALL with or without complete remission after salvage therapy following poor response to induction therapy - -> ALL after haematological or molecular relapse. - Fit for transplant according to physician judgement. - No history of cardiac disease and absence of active symptoms, otherwise, documented left ventricular ejection fraction >=40%. - No history of chronic pulmonary disease and absence of dyspnea - -> Otherwise, documented diffusion lung capacity for carbon monoxide (DLCO) >=40% or FEV1/FVC >= 50% despite appropriate treatment Availability of >=1 unrelated donor with a single allele or antigen mismatch at HLA-A, -B, -C, or -DRB1 and no concurrent DQB1 mismatch (9/10) shown by confirmatory typing - Availability of at least one haploidentical donor meeting the following criteria: - -> Donor is a biologic parent / child of the patient or haploidentity has been confirmed for patient’s relatives by HLA-Typing.

	- -> The donor has expressed his / her will to donate, and has no contraindications against a stem cell donation by medical history - -> Donor age is >=18 years and <=75 years
Ausschlusskriterien	- Relapse or graft failure after a first allogeneic transplantation. - Thymic ALL in first complete remission - Severe organ dysfunction defined by either of the following three criteria: - -> Patients who receive supplementary continuous oxygen. - -> Serum bilirubin >1.5 x ULN (if not considered Gilbert-Syndrome) or ASAT/ALAT >5 x ULN. - -> Estimated Glomerular Filtration Rate (GFR) < 40 ml/min, where: Estimated GFR (mL/min/1.73 m2) = 186 x (Serum Creatinine)-1.154 x (age in years)- 0.203 x (0.742 if patient is female) x (1.212 if patient is black) - Uncontrolled infection at the time of enrollment. - Pregnant or breast-feeding women - An HLA-identical sibling donor or 8/8 (HLA-A, -B, -C, or -DRB1) matched unrelated donor is available and suitable to donate prior to randomization - Men unable or unwilling to use adequate contraception methods from enrollment to minimum of six months after the last dose of chemotherapy - Women of childbearing potential except those who fulfill the following criteria: Post-menopausal or post-operative or continuous and correct application of a contraception method with a Pearl Index <1% or sexual abstinence or vasectomy of the sexual partner - Simultaneous participation in another clinical trial.
Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	05.04.2019
Sponsoren	DKMS
Förderer	DKMS
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT03275636 European Clinical Trials Database - EUDRACT2015-005399-12