Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

CIK-Cell Study

Öffentlicher Titel	Phase I/II Studie zu IL-15 aktivierten Cytokininduzierten Killerzellen (CIK) bei akuten Leukämien und MDS nach allogener SZT
Wissenschaftl. Titel	A prospective phase I/II study to investigate the feasibility, safety and efficacy of IL-15 activated cytokine induced killer (CIK) cells in relapsing patients with acute leukemia or myelodysplastic syndromes after allogeneic stem cell transplantation
Kurztitel	CIK-Cell Study
Studiennummer KN/ELN	LN_NN_2016_646
Studiengruppe	NN
Studienart	multizentrisch, einarmig, prospektiv, offen
Studienphase	Phase I/II
Erkrankung	Akute lymphatische Leukämie (ALL) - Alle Subtypen Myelodysplastisches Syndrom (MDS) - Alle Subtypen
Leukämiestadium	rezidiviert/refraktär
Einschlusskriterien	- Acute leukemia and MDS patients with molecular relapse in peripheral blood (PB) or bone marrow (BM) samples obtained during monitoring for relapse after allogeneic SCT - 1. MRD detected by Ig/TCR gene rearrangements testing or - 2. confirmed mixed chimerism (MC) >= 1%, or - 3. levels >= 10-4 of BCR-ABL/ABL ratio will trigger CIK cell interventions - Respecting MC, MC >= 1% of autologous signals in PB samples confirmed by another PB or BM sample within one week. Patients with MC >= 1% of autologous signals in CD33+ and/or CD34+ subpopulations in PB samples confirmed by BM analyses within one week. Acute leukemia and MDS patients with MC >= 1% of autologous signals including signals in CD33+ and/or CD34+ subpopulations in BM samples - Patients without immunosuppressive agents and steroids - Patients without chemo- or immune therapy, except patients with thyrosine-kinase inhibitors (TKI) for reatment of BCR-ABL positive leukemias - Patients with < grade II GvHD - Patients with Karnowsky or Lansky performance status >= 50%. - Patients and/or his/her legal representative having reviewed the patient information/informed consent form and have had their questions answered and have given written informed consent
Ausschlusskriterien	- Acute leukemia and MDS patients with hematologic relapse < day 120 after allogeneic stem cell transplantation - Patients with more than 5% malignant cells in bone marrow analyses - Patients with immunosuppressive agents or steroids - Patients with chemo- or immune therapy, except patients with thyrosine-kinase inhibitors (TKI) for BCR-ABL positive leukemias - Patients with >= grade II GvHD - Patients with Karnowsky or Lansky performance status < 50% - Patients and/or his/her legal representative having reviewed the patient information/informed consent form and have had their questions answered and have not given written informed consent - HIV-positive patients - HBV/HCV patients - Patients with prior solid organ transplantation

	- Patients treated with any other investigational product within the last 28 days or five half-lives (whichever is longer). - Hypersensitivity to any component of the study drug - Female patients of child-bearing potential not agreeing to use a highly effective method of birth control resulting in a low failure rate (i.e. < 1%) when used consistently and correctly - Male patients with female partners of childbearing potential not agreeing to use a highly effective method birth control resulting in a low failure rate (i.e. < 1%) when used consistently and correctly - Pregnancy/Breastfeeding - Patients with severe infections or signs/symptoms of infection within 2 weeks prior to study start
Alter	<= 75 Jahre(0-80J)
Status	Aktiv
Beginn der Rekrutierung	24.03.2016
Sponsoren	Goethe-Universität Frankfurt am Main
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT02752243 European Clinical Trials Database - EUDRACT2013-005446-11