

KURZPROTOKOLL
HaploMUD

Öffentlicher Titel	Phase II Studie zu Spendertypen für die allogene Stammzelltransplantation bei akuter Leukämie
Wissenschaftl. Titel	Matched Unrelated vs. Haploidentical Donor for Allogeneic Stem Cell Transplantation in Patients with Acute Leukemia with identical GVHD Prophylaxis – A Randomized, Prospective European Trial
Kurztitel	HaploMUD
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Blut: Akute lymphatische Leukämie (ALL): sonstige Studien für akute Leukämien Blut: Myeloische Neoplasien/Dysplasien: Myelodysplastische Syndrome (MDS) Blut: Stammzelltransplantation: Allogene Stammzelltransplantation Blut: Akute myeloische Leukämie (AML): sonstige Studien für akute Leukämien
Einschlusskriterien	- Acute Myeloid Leukemia (AML) intermediate or high risk according to ELN or Acute Lymphoblastic Leukemia (ALL) high risk according to ESMO guidelines in 1. CR or AML/ALL in 2. CR, or high risk MDS (according to IPSS-R) in 1. CR or 2. CR. - Patients age: 18 - 70 years at time of inclusion (female and male). - Patients understand and voluntarily sign an informed consent form. - ECOG 2. - 10/10 HLA-matched unrelated donor and haploidentical (5/10 and 8/10 HLA) relative matched donor available at least 4 weeks after completion of induction and/or consolidation therapy. - Females/Males who agree to comply with the applicable contraceptive requirements of the protocol.
Ausschlusskriterien	- Severe renal, hepatic, pulmonary or cardiac disease, such as: total bilirubin, SGPT or SGOT > 3 times upper the normal level left ventricular ejection fraction < 30 % creatinine clearance < 30 ml/min DLCO < 35 % and/or receiving supplementary continuous oxygen - Positive serology for HIV. - Pregnant or lactating women (positive serum pregnancy test). - Age < 18 and 71 years. - Uncontrolled invasive fungal infection at time of screening (baseline). - Serious psychiatric or psychological disorders. - Participation in another study with ongoing use of unlicensed investigational product from 28 days before study enrollment. - Uncontrolled severe autoimmune disease or uncontrolled other malignancy. - Availability of an HLA-identical sibling as donor source.
Alter	18 - 70 Jahre
Prüfzentren	Innere Medizin 2 (Aktiv) Hämatologie / Medizinische Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Sandra Wagner-Schernick Tel: 069 6301-83209 sandra.wagner-schernick@unimedizin-ffm.de

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Sponsor

University Medical Center Hamburg-Eppendorf

Förderer

DKMS

**Registrierung in anderen
Studienregistern**

ClinicalTrials.gov NCT04232241
EudraCT 2017-002331-41 (primäres Register)

Links

[Studiendokumente zum Download \(roXtra\)](#)
[Zu den Ein- und Ausschlusskriterien](#)