

KURZPROTOKOLL
ALL SCTped 2012Forum

Öffentlicher Titel	Allogene Stammzelltransplantation bei Kindern und Jugendlichen mit ALL
Wissenschaftl. Titel	ALL SCTped 2012 FORUM Allogeneic Stem Cell Transplantation in Children and Adolescents with Acute Lymphoblastic Leukaemia
Kurztitel	ALL SCTped 2012Forum
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase IV
Erkrankung	Kinder: Leukämien und Lymphome: Stammzelltransplantation
Ziele	- To compare outcome of children with ALL who received a TBI containing regimen versus irradiation free conditioning followed by HSCT. - To compare outcome after mismatched donor HSCT using mismatched unrelated donors, haplo-identical family donors or mismatched cord blood.
Einschlusskriterien	- age at time of conditioning less than 18 years - indication for allogeneic HSCT according to the national frontline protocols (Germany: AIEOP-BFM ALL 2009 and IntReALL SR 2010) - complete remission (CR) before SCT - written consent of the parents (legal guardian) and, if necessary, the minor patient via "Informed Consent Form" - no pregnancy - no secondary malignancy - no previous HSCT - HSCT is performed in a study participating centre
Ausschlusskriterien	- Non Hodgkin-Lymphoma - ALL with extramedullary involvement with indication for TBI - Trisomy 21 - Severe renal impairment (GFR<30% predicted for age) - Severe liver insufficiency - pregnancy - The whole protocol or essential parts are declined either by patient himself/herself or the respective legal guardian - No consent is given for saving and propagation of anonymous medical data for study reasons - Severe concomitant disease that does not allow treatment according to the protocol at the investigator's discretion: e.g. malformation syndromes, cardiac malformations, metabolic disorders; Renal impairment (< 30% of normal glomerular filtration rate) Severe pulmonary, hepatic or cardiac impairment due to toxicity or infection - Karnofsky / Lansky score < 50% - Subjects unwilling or unable to comply with the study procedures
Alter	<= 18 Jahre
Prüfzentren	Universitätsmedizin Frankfurt (Nachbeobachtung) Klinik für Kinder- und Jugendmedizin Theodor-Stern-Kai 7 60590 Frankfurt am Main Prof. Dr. med. Peter Bader Tel: 069 6301-7542 Fax: 069 6301-4202 peter.bader@unimedizin-fm.de

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Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01949129 (primäres Register) EudraCT 2012-003032-22
Therapie	Stammzelltransplantation
Links	Weiterführende Informationen