KURZPROTOKOLL
IntReALL SR 2010

Öffentlicher Titel	Internationale Pädiatrische Phase III Studie bei Standard Risiko Relapsed ALL
Wissenschaftl. Titel	IntReALL SR 2010 (International Study for Treatment of Standard Risk Childhood Relapsed ALL 2010) A randomized Phase III Study Conducted by the Resistant Disease Committee of the International BFM Study Group
Kurztitel	IntReALL SR 2010
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase III
Erkrankung	Kinder: Leukämien und Lymphome: Rezidiviert/refraktär
Ziele	- The main goal of this study is to improve the outcome of children and adolescents with standard risk first relapsed acute lymphoblastic leukemia. Furthermore, goal is to set up a large international study group platform allowing for optimization of standard treatment strategies and integration of new agents.
Einschlusskriterien	- Morphologically confirmed diagnosis of 1st relapsed precursor B-cell or T-cell ALL - Children less than 18 years of age at inclusion - Meeting SR criteria: late isolated or late/early combined BCP BM relapse, any late/early isolated extramedullary relapse - Patient enrolled in a participating centre - Written informed consent - Start of treatment falling into the study period - No participation in other clinical trials 30 days prior to study enrolment that interfere with this protocol, except trials for primary ALL - Inclusion criteria specific for the epratuzumab randomization: - Precursor B-cell Immunophenotype of ALL - M1 or M2 bone marrow status after induction
Ausschlusskriterien	- BCR-ABL / t(9;22) positive ALL - Pregnancy or positive pregnancy test (urine sample positive for -HCG > 10 U/l) - Sexually active adolescents not willing to use highly effective contraceptive method (pearl index <1) until 2 years after end of antileukemic therapy - Breast feeding - Relapse post allogeneic stem-cell transplantation - 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 pseudonymized 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) - Karnovsky / Lansky score < 50% - Subjects unwilling or unable to comply with the study procedures - Subjects who are legally detained in an official institute
Alter	<= 18 Jahre
Fallzahl	1242

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Prüfzentren	**Universitätsklinikum Frankfurt** (Nachbeobachtung) Klinik für Kinder- und Jugendmedizin Theodor-Stern-Kai 7 60590 Frankfurt am Main Gudrun Sach Tel: 069 6301-83643 gudrun.sach@kgu.de **Kinder- und Jugendmedizin** (Nachbeobachtung) Schwerpunkt Onkologie, Hämatologie und Hämostaseologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Gudrun Sach Tel: 069 6301-83643 gudrun.sach@kgu.de
Förderer	Universitätsmedizin Berlin, Charite
Registrierung in anderen Studienregistern	EudraCT 2012-000793-30
Therapie	- SR arm A (ALL-REZ BFM 2002 arm Prot II-IDA): Induction: SIA (F1, F2); Post induction: SCA1 and SCA2 ± epratuzumab (8x360mg/m²/ 1 hrs IV weekly, week 5-12), 5 courses SCA3-7 (R1/2/1/2/1), 24 months maintenance (6MP, MTX) with 6 x TIT / 4 weeks. Cranial irradiation 18Gy for CNS relapse. - SR arm B (UK-R3, arm mitoxantrone): Induction: SIB (phase I); Post induction: SCB1 and SCB2 (R3-consolidation and intensification) ± epratuzumab (8x360mg/m²/ 1hrs IV weekly, week 6-13), 2 courses SCB3-4 (R3-interim maintenance 1 and 2), 24 months maintenance (6MP, MTX, 4-weekly VCR/DEX/IT reinduction pulses). Cranial irradiation 18 for CNS disease. - SCT indications: Any donor Arm A with MRD >= 10-3 after SIA, arm B with >= 10-4 after SIB. Matched donor any early combined, isolated extramedullary relapse or patients without MRD results. SCT is scheduled at week 16