

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: Rezidiert/refraktär
Ziele	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- 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:<ul style="list-style-type: none">- Precursor B-cell Immunophenotype of ALL- M1 or M2 bone marrow status after induction
Ausschlusskriterien	<ul style="list-style-type: none">- 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

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Förderer

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**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 $\geq 10^{-3}$ after SIA, arm B with $\geq 10^{-4}$ after SIB. Matched donor any early combined, isolated extramedullary relapse or patients without MRD results. SCT is scheduled at week 16