

## **KURZPROTOKOLL** **IntReALL SR 2010**

<b>Öffentlicher Titel</b>	Internationale Pädiatrische Phase III Studie bei Standard Risiko Relapsed ALL
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	IntReALL SR 2010
<b>Studienart</b>	multizentrisch, prospektiv, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Kinder: Leukämien und Lymphome: Rezidiert/refraktär
<b>Ziele</b>	<ul style="list-style-type: none"><li>- 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.</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Morphologically confirmed diagnosis of 1st relapsed precursor B-cell or T-cell ALL</li><li>- Children less than 18 years of age at inclusion</li><li>- Meeting SR criteria: late isolated or late/early combined BCP BM relapse, any late/early isolated extramedullary relapse</li><li>- Patient enrolled in a participating centre</li><li>- Written informed consent</li><li>- Start of treatment falling into the study period</li><li>- No participation in other clinical trials 30 days prior to study enrolment that interfere with this protocol, except trials for primary ALL</li><li>- Inclusion criteria specific for the epratuzumab randomization:<ul style="list-style-type: none"><li>- Precursor B-cell Immunophenotype of ALL</li><li>- M1 or M2 bone marrow status after induction</li></ul></li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- BCR-ABL / t(9;22) positive ALL</li><li>- Pregnancy or positive pregnancy test (urine sample positive for -HCG &gt; 10 U/l)</li><li>- Sexually active adolescents not willing to use highly effective contraceptive method (pearl index &lt;1) until 2 years after end of antileukemic therapy</li><li>- Breast feeding</li><li>- Relapse post allogeneic stem-cell transplantation</li><li>- The whole protocol or essential parts are declined either by patient himself/herself or the respective legal guardian</li><li>- No consent is given for saving and propagation of pseudonymized medical data for study reasons</li><li>- 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)</li><li>- Karnovsky / Lansky score &lt; 50%</li><li>- Subjects unwilling or unable to comply with the study procedures</li><li>- Subjects who are legally detained in an official institute</li></ul>
<b>Alter</b>	<= 18 Jahre
<b>Fallzahl</b>	1242

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**Prüfzentren**

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**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/m<sup>2</sup>/ 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/m<sup>2</sup>/ 1 hrs 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