

**KURZPROTOKOLL**  
**ALL SCTped 2012Forum**

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| <b>Öffentlicher Titel</b>   | Allogene Stammzelltransplantation bei Kindern und Jugendlichen mit ALL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Wissenschaftl. Titel</b> | ALL SCTped 2012 FORUM Allogeneic Stem Cell Transplantation in Children and Adolescents with Acute Lymphoblastic Leukaemia                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Kurztitel</b>            | ALL SCTped 2012Forum                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Studienart</b>           | multizentrisch, prospektiv, Therapiestudie, randomisiert, zweiarmig, Investigator Initiated Trial (IIT)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Studienphase</b>         | Phase IV                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Erkrankung</b>           | Kinder: Leukämien und Lymphome: Stammzelltransplantation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Ziele</b>                | <ul style="list-style-type: none"><li>- To compare outcome of children with ALL who received a TBI containing regimen versus irradiation free conditioning followed by HSCT.</li><li>- To compare outcome after mismatched donor HSCT using mismatched unrelated donors, haplo-identical family donors or mismatched cord blood.</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Einschlusskriterien</b>  | <ul style="list-style-type: none"><li>- age at time of conditioning less than 18 years</li><li>- indication for allogeneic HSCT according to the national frontline protocols (Germany: AIEOP-BFM ALL 2009 and IntReALL SR 2010)</li><li>- complete remission (CR) before SCT</li><li>- written consent of the parents (legal guardian) and, if necessary, the minor patient via "Informed Consent Form"</li><li>- no pregnancy</li><li>- no secondary malignancy</li><li>- no previous HSCT</li><li>- HSCT is performed in a study participating centre</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Ausschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Non Hodgkin-Lymphoma</li><li>- ALL with extramedullary involvement with indication for TBI</li><li>- Trisomy 21</li><li>- Severe renal impairment (GFR&lt;30% predicted for age)</li><li>- Severe liver insufficiency</li><li>- pregnancy</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 anonymous 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; Renal impairment (&lt; 30% of normal glomerular filtration rate) Severe pulmonary, hepatic or cardiac impairment due to toxicity or infection</li><li>- Karnofsky / Lansky score &lt; 50%</li><li>- Subjects unwilling or unable to comply with the study procedures</li></ul> |
| <b>Alter</b>                | <= 18 Jahre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Prüfzentren</b>          | <b>Kinder- und Jugendmedizin</b> (Nachbeobachtung)<br>Schwerpunkt Stammzelltransplantation, Immunologie und Intensivmedizin<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Prof. Dr. med. Peter Bader<br>Tel: 069 6301-7542<br>Fax: 069 6301-4202<br><a href="mailto:peter.bader@unimedizin-ffm.de">peter.bader@unimedizin-ffm.de</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT01949129 (primäres Register)<br>EudraCT 2012-003032-22 |
| <b>Therapie</b>                                  | Stammzelltransplantation                                                     |
| <b>Links</b>                                     | <a href="#">Weiterführende Informationen</a>                                 |