

## **KURZPROTOKOLL** **GMALL-MOLACT1-BLINA**

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| <b>Öffentlicher Titel</b>   | Blinatumomab bei MRD-positiver B-Vorläufer ALL  |
| <b>Wissenschaftl. Titel</b> | A multicenter, single-arm study to assess the efficacy, safety, and tolerability of the BiTE® antibody blinatumomab in adult patients with minimal residual disease (MRD) of B-precursor acute lymphoblastic leukemia (Blast Successor Trial)   |
| <b>Kurztitel</b>            | GMALL-MOLACT1-BLINA   |
| <b>Studienart</b>           | multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)  |
| <b>Studienphase</b>         | Phase II  |
| <b>Erkrankung</b>           | Blut: Akute lymphatische Leukämie (ALL): Rezidiert/refraktär  |
| <b>Einschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Patients with CD19 positive B-precursor ALL in complete hematological remission defined as less than 5% blasts in bone marrow after at least three intense chemotherapy blocks (e.g., GMALL induction I-II/consolidation I).</li><li>- Presence of minimal residual disease (MRD) at a level of <math>\geq 10^{-4}</math> (molecular failure or molecular relapse) in an assay with a minimum sensitivity of <math>10^{-4}</math> documented after an interval of at least 2 weeks from last systemic chemotherapy</li><li>- For evaluation of MRD patients must have at least one molecular marker based on individual rearrangements of immunoglobulin, TCR-genes or other suitable genes evaluated by the reference laboratory of the trial</li><li>- Bone marrow function as defined below: (a) ANC (Neutrophils) <math>\geq 1,000/\mu\text{L}</math>; (b) Platelets <math>\geq 50,000/\mu\text{L}</math> (transfusion permitted); (c) HB level <math>\geq 9\text{g/dl}</math> (transfusion permitted)</li><li>- Renal and hepatic function as defined below: (a) AST (GOT), ALT (GPT), and AP <math>&lt; 5</math> x upper limit of normal (ULN); (b) Total bilirubin <math>&lt; 1.5</math> x ULN (unless related to Gilbert's Meulengracht disease); (c) Creatinine <math>&lt; 1.5</math> x ULN; (d) Creatinine clearance <math>\geq 60</math> mL/min (e.g. calculated according Cockcroft&amp;Gault)</li><li>- Negative HIV test, negative hepatitis B (HbsAg) and hepatitis C virus (anti-HCV) test</li><li>- Negative pregnancy test in women of childbearing potential</li><li>- ECOG Performance Status 0 or 1</li><li>- Age <math>\geq 18</math> years</li><li>- Ability to understand and willingness to sign a written informed consent</li><li>- Signed and dated written informed consent is available</li><li>- Participation in the registry of the German Multicenter Study Group for Adult ALL (GMALL)</li></ul> |
| <b>Ausschlusskriterien</b>  | <ul style="list-style-type: none"><li>- Ph/BCR-ABL positive ALL</li><li>- Presence of circulating blasts or current extramedullary involvement by ALL</li><li>- History or presence of clinically relevant CNS pathology (e.g. seizure, paresis, aphasia, cerebrovascular ischemia/hemorrhage, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome or psychosis)</li><li>- Current detection of ALL blast cells in cerebro-spinal fluid</li><li>- History of or active relevant autoimmune disease</li><li>- Systemic cancer chemotherapy within 2 weeks prior to study treatment (except for intrathecal prophylaxis)</li><li>- Radiotherapy within 4 weeks prior to study treatment</li><li>- Live vaccination within 2 weeks before the start of study treatment</li><li>- Autologous hematopoietic stem cell transplantation (SCT) within six weeks prior to study treatment</li><li>- Allogeneic SCT within 12 weeks before the start of study treatment</li></ul>  |

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- Any active acute Graft-versus-Host Disease (GvHD), grade 2-4 according to the Glucksberg criteria or active chronic GvHD requiring systemic treatment
- Any systemic therapy against GvHD within 2 weeks before start of study treatment
- Therapy with monoclonal antibodies (rituximab, alemtuzumab) within 4 weeks prior to study treatment
- Treatment with any investigational product within four weeks prior to study treatment
- Previous treatment with blinatumomab or other anti-CD19-therapy
- Known hypersensitivity to immunoglobulins or to any other component of the study drug formulation
- History of malignancy other than ALL diagnosed within 5 years prior to start of protocol-specified therapy with the exception of: (a) Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease; (b) Adequately treated cervical carcinoma in situ without evidence of disease; (c) Adequately treated breast ductal carcinoma in situ without evidence of disease; (d) Prostatic intraepithelial neoplasia without evidence of prostate cancer
- Active infection, any other concurrent disease or medical condition that are deemed to interfere with the conduct of the study as judged by the investigator
- Nursing women
- Woman of childbearing potential and is not willing to use 2 highly effective methods of contraception while receiving study treatment and for an additional 3 months after the last dose of study treatment.
- Male who has a female partner of childbearing potential, and is not willing to use 2 highly effective forms of contraception while receiving study treatment and for at least an additional 3 months after the last dose of study treatment

**Alter** 18 Jahre und älter

**Molekularer Marker** CD19

**Fallzahl** 30

**Prüfzentren**

**Innere Medizin 2** (Rekrutierung beendet)  
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EudraCT 2015-000733-76

***KURZPROTOKOLL  
GMALL-MOLACT1-BLINA***

**Links**

[Studiendokumente zum Download \(roXtra\)](#)  
[Zu den Ein- und Ausschlusskriterien](#)