

KURZPROTOKOLL
GMALL-MOLACT1-BLINA

Öffentlicher Titel	Blinatumomab bei MRD-positiver B-Vorläufer ALL
Wissenschaftl. Titel	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)
Kurztitel	GMALL-MOLACT1-BLINA
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Blut: Akute lymphatische Leukämie (ALL): Rezidiert/refraktär
Einschlusskriterien	- 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). - Presence of minimal residual disease (MRD) at a level of $\geq 10^{-4}$ (molecular failure or molecular relapse) in an assay with a minimum sensitivity of 10^{-4} documented after an interval of at least 2 weeks from last systemic chemotherapy - 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 - Bone marrow function as defined below: (a) ANC (Neutrophils) $\geq 1,000/\mu\text{L}$; (b) Platelets $\geq 50,000/\mu\text{L}$ (transfusion permitted); (c) HB level $\geq 9\text{g/dl}$ (transfusion permitted) - Renal and hepatic function as defined below: (a) AST (GOT), ALT (GPT), and AP $< 5 \times$ upper limit of normal (ULN); (b) Total bilirubin $< 1.5 \times$ ULN (unless related to Gilbert's Meulengracht disease); (c) Creatinine $< 1.5 \times$ ULN; (d) Creatinine clearance $\geq 60 \text{ mL/min}$ (e.g. calculated according Cockcroft&Gault) - Negative HIV test, negative hepatitis B (HbsAg) and hepatitis C virus (anti-HCV) test - Negative pregnancy test in women of childbearing potential - ECOG Performance Status 0 or 1 - Age ≥ 18 years - Ability to understand and willingness to sign a written informed consent - Signed and dated written informed consent is available - Participation in the registry of the German Multicenter Study Group for Adult ALL (GMALL)
Ausschlusskriterien	- Ph/BCR-ABL positive ALL - Presence of circulating blasts or current extramedullary involvement by ALL - 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) - Current detection of ALL blast cells in cerebro-spinal fluid - History of or active relevant autoimmune disease - Systemic cancer chemotherapy within 2 weeks prior to study treatment (except for intrathecal prophylaxis) - Radiotherapy within 4 weeks prior to study treatment - Live vaccination within 2 weeks before the start of study treatment - Autologous hematopoietic stem cell transplantation (SCT) within six weeks prior to study treatment - Allogeneic SCT within 12 weeks before the start of study treatment

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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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Links

[Studiendokumente zum Download \(roXtra\)](#)

[Zu den Ein- und Ausschlusskriterien](#)