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): Rezidiviert/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 >=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) >= 1,000/µL; (b) Platelets >= 50,000/µL (transfusion permitted); (c) HB level >= 9g/dl (transfusion permitted)
- Renal and hepatic function as defined below: (a) AST (GOT), ALT (GPT), and AP < 5 x upper limit of normal (ULN); (b) Total bilirubin < 1.5 x ULN (unless related to Gilbert's Meulengracht disease); (c) Creatinine < 1.5x ULN; (d) Creatinine clearance >= 60 mL/min (e.g. calculated according Cockroft&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

- 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) Hämatologie / Medizinische Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Studienkoordination GMALL-Molact-1-Blina molact1-blina@med.uni-frankfurt.de
Sponsor	Goethe-Universität Frankfurt
Förderer	AMGEN GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03109093 EudraCT 2015-000733-76
Links	Studiendokumente zum Download (roXtra) Zu den Ein- und Ausschlusskriterien