KURZPROTOKOLL
EWALL-BOLD

Öffentlicher Titel	Phase II Studie zu Blinatumomab und dosisreduzierter Chemotherapie bei älteren Patienten mit Vorläufer-B-ALL
Wissenschaftl. Titel	Phase II trial for the treatment of older patients with newly diagnosed CD19 positive, Ph/BCR-ABL negative B-precursor acute lymphoblastic leukemia with sequential dose reduced chemotherapy and Blinatumomab
Kurztitel	EWALL-BOLD
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Blut: Akute lymphatische Leukämie (ALL): Neu diagnostiziert / de novo
Einschlusskriterien	- Patients with newly diagnosed CD19 positive B-precursor ALL - Greater than 25 % blasts in bone marrow - Eastern Cooperative Oncology Group (ECOG) performance status <= 2 - Charlson comorbidity score <= 2 - Age > 55 and < 75 years at the time of informed consent - Renal and hepatic function as defined below: a).AST (SGOT), ALT(SGPT) and AP < 5x upper limit of normal (UNL) (unless related to leukemic liver infiltration by investigator assessment) b). Total bilirubin < 1.5x ULN (unless related to Gilbert's Meulengracht disease) c). Creatinine < 1.5x ULN d). Creatinine clearance >= 50 mL/min (e.g. calculated according Cockroft & Gault) - Negative pregnancy test in women of childbearing potential - Ability to understand and willingness to sign a written informed consent - For Germany: Participation in the registry of the German Multicenter Study Group for Adult ALL (GMALL)
Ausschlusskriterien	- Antileukemic pretreatment (GMALL prephase with dexamethasone and cyclophosphamide allowed) - History of malignancy other than ALL within 5 years prior to start of protocol-specified therapy with the exception of: a) Malignancy treated with curative intent and with no known active disease present for 2 years before enrollment and felt to be at low risk for recurrence by the treating physician including b). Adequately treated non-melanoma skin cancer or lentigo maligna without evidence of disease c) Adequately treated cervical carcinoma in situ without evidence of disease d). Adequately treated breast ductal carcinoma in situ without evidence of disease e). Prostatic intraepithelial neoplasia without evidence of prostate cancer - History or presence of clinically relevant (per investigator's assessment) CNS pathology such as epilepsy, childhood or adult seizure, paresis, aphasia, stroke, severe brain injuries, dementia, Parkinson's disease, cerebellar disease, organic brain syndrome or psychosis - Active ALL in the CNS confirmed by CSF analysis) or testes (clinical diagnosis) or other extramedullary involvement; non-bulky lymph node (< 7.5 cm diameter) involvement will be accepted - Current autoimmune disease or history of autoimmune disease with potential CNS involvement - Known exclusion criteria to recommended chemotherapy - Known positivity of HIV, hepatitis B (HbsAG) or hepatitis C virus (anti-HCV) - Subject received prior anti-CD19 therapy - Live vaccination within 2 weeks before the start of study treatment

- Known hypersensitivity to immunoglobulins or to any other component of the study drug formulation: Subject has known sensitivity to immunoglobulins or any of the products or components to be administered during dosing
- Currently receiving treatment in another investigational device or drug study or less than 30 days since ending treatment on another investigational device or drug study(s). Thirty days is calculated from day 1 of protocol-specified therapy
- Subject likely to not be available to complete all protocol-required study visits or procedures, including follow-up visits, and/or to comply with all required study procedures to the best of the subject's and investigator's knowledge
- History or evidence of any other clinically significant disorder, condition or disease (with the exception of those outlined above) that, in the opinion of the investigator would pose a risk to subject safety of interfere with the study evaluation, procedures or completion
- Woman of childbearing potential and is not willing to use a highly effective method 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 protocol-specified therapy and for at least an additional 3 months after the last dose of protocol-specified therapy.

Alter	56 - 74 Jahre
Molekularer Marker	CD19
Prüfzentren	**Universitätsmedizin Frankfurt** (Rekrutierung beendet) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main EWALL-BOLD Studienkoordination ewall-bold@em.uni-frankfurt.de
Sponsor	Universität Frankfurt
Förderer	AMGEN GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03480438 (primäres Register) EudraCT 2017-002853-13
Links	Studiendokumente zum Download (roXtra) Zu den Ein- und Ausschlusskriterien