KURZPROTOKOLL
ALL Rez HR- Blinatumomab

Öffentlicher Titel	Phase III Studie zu Blinatumomab vs konventionelle Chemotherapie bei rezidivierter Hochrisiko B-Vorläufer-ALL
Wissenschaftl. Titel	A Randomized, Open-label, Controlled Phase 3 Adaptive Trial to Investigate the Efficacy, Safety, and Tolerability of the BiTE Antibody Blinatumomab as Consolidation Therapy Versus Conventional Consolidation Chemotherapy in Pediatric Subjects With High-risk First Relapse B-precursor Acute Lymphoblastic Leukemia (ALL)
Kurztitel	ALL Rez HR- Blinatumomab
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Kinder: Leukämien und Lymphome: Rezidiviert/refraktär
Einschlusskriterien	- Subjects with Philadelphia chromosome negative (Ph-) high-risk (HR) first relapse B-precursor ALL (as defined by I-BFM SG/IntReALL criteria) - Subjects with M1 or M2 marrow at the time of randomization, - Age > 28 days and < 18 years at the time of informed consent/assent - Subject's legally acceptable representative has provided informed consent when the subject is legally too young to provide informed consent and the subject has provided written assent based on local regulations and/or guidelines prior to any study-specific activities/procedures being initiated - Availability of the following material from relapse diagnosis for central analysis of MRD by PCR: clone-specific primers and reference DNA, as well as primer sequences and analyzed sequences of clonal rearrangements.
Ausschlusskriterien	- Clinically relevant CNS pathology requiring treatment (eg, unstable epilepsy) - Evidence of current CNS (CNS 2, CNS 3) involvement by ALL - Subjects with CNS relapse at the time of relapse are eligible if CNS is successfully treated prior to enrollment - Abnormal renal or hepatic function prior to start of treatment (day 1) as defined below: a. Serum creatinine levels above upper limit of normal, based on the normal ranges for age and gender of the local laboratories. b. Direct bilirubin > 1.5 mg/dL (for subjects with total bilirubin < 1.50 mg/dL, measurement of direct bilirubin is not required) prior to start of treatment (unless related to Gilbert's or Meulengracht disease) - Peripheral neutrophils < 500/L prior to start of treatment - Peripheral platelets < 50,000/L prior to start of treatment - Currently receiving treatment in another investigational device or drug study or less than 4 weeks since ending treatment on another investigational device or drug study(s), procedures required by IntReALL HR guidelines are allowed - Chemotherapy related toxicities that have not resolved to <= grade 2 - Symptoms and/or clinical signs and/or radiological and/or sonographic signs that indicate an acute or uncontrolled chronic infection, any other concurrent disease or medical condition that could be exacerbated by the treatment or would seriously complicate compliance with the protocol - Known infection with human immunodeficiency virus (HIV) - Known hypersensitivity to immunoglobulins or any of the products or components to be administered during dosing - Post-menarchal female subject who is pregnant or breastfeeding, or is planning to become pregnant or breastfeed while receiving protocol-specified therapy and for at least 6 months after the last dose of blinatumomab or for 12 months after the last dose of chemotherapy

	- Post-menarchal female subject who is not willing to practice true sexual abstinence or use a highly effective form of contraception while receiving protocol-specified therapy and for at least 6 months after the last dose of blinatumomab or for 12 months after the last dose of chemotherapy - Sexually mature male subject who is not willing to practice true sexual abstinence or use a condom with spermicide while receiving protocol-specified therapy and for at least 6 months thereafter. In countries where spermicide is not available, a condom without spermicide is acceptable - Sexually mature male subject who is not willing to abstain from sperm donation while receiving protocol-specified therapy and for at least 6 months thereafter - 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 or Amgen physician, if consulted, would pose a risk to subject safety or interfere with the study evaluation, procedures, or completion - Placed into an institution due to juridical or regulatory ruling.
Alter	1 Monat bis 17 Jahre
Fallzahl	320
Prüfzentren	**Universitätsklinikum Frankfurt** (Geschlossen) Klinik für Kinder- und Jugendmedizin Theodor-Stern-Kai 7 60590 Frankfurt am Main Gudrun Sach Tel: 069 6301-83643 gudrun.sach@kgu.de **Kinder- und Jugendmedizin** (Geschlossen) Schwerpunkt Onkologie, Hämatologie und Hämostaseologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Gudrun Sach Tel: 069 6301-83643 gudrun.sach@kgu.de
Sponsor	AMGEN GmbH
Registrierung in anderen Studienregistern	EudraCT 2014-002476-92 ClinicalTrials.gov NCT02393859