Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL
GMALL 08/2013

Öffentlicher Titel	Studie zur Therapieoptimierung bei neu diagnostizierter ALL und LBL
Wissenschaftl. Titel	Therapieoptimierung bei erwachsenen Patienten mit neu diagnostizierter akuter lymphatischer Leukämie (ALL) oder lymphoblastischem Lymphom (LBL) durch individualisierte, gezielte und intensivierte Therapie - Eine Phase IV-Studie mit einem Phase III-Teil zur Evaluation der Sicherheit und Wirksamkeit von Nelarabin bei T-ALL
Kurztitel	GMALL 08/2013
Studiennummer KN/ELN	LN_GMALL_2016_592
Studiengruppe	GMALL
Studienart	multizentrisch, randomisiert, mehrarmig, prospektiv, offen
Studienphase	Phase III/IV
Erkrankung	Akute lymphatische Leukämie (ALL) - Alle Subtypen
Leukämiestadium	de novo/non-treated
Ziele	- To improve event free survival (EFS), remission duration (RD), disease free survival (DFS) and overall survival (OS) compared with the previous trial GMALL 07/2003 - To evaluate the role of CNS radiation and the role of chemotherapy alone in high risk ALL in molecular remission by randomised evaluation - To evaluate the feasibility of the entire treatment concept (i.e. adherence to schedule, administration of single and combination chemotherapy, maintenance therapy) - To evaluate feasibility and tolerability of nelarabine (IMP) as part of consolidation treatment in T-ALL - To perform prospective and concomitant monitoring of comorbidities and specifically defined serious adverse events - To evaluate an innovative overall approach to optimize treatment of a rare, biologically diverse disease by use of subgroup specific targeted and experimental substances within the main trial and in associated studies - To set up an interlinked biomaterial bank to prospectively evaluate molecular genetic risk factors and carry out scientific accompanying projects
Einschlusskriterien	- Acute lymphoblastic leukemia all subtypes except burkitt leukemia, blasts in BM 25% or - Lymphoblastic lymphoma (B- or T-lineage), blasts in BM <25% - Age: 18 - 55 years - Written Informed consent to participate in the study and the GMALL registry - Women of childbearing potential (WOCBP) and male sexual partners of WOCBP must be willing to use an effective method of contraception (Pearl-Index < 1%) during the study and at least 6 months thereafter
Ausschlusskriterien	- Serious complications (leukemia associated) or concomitant diseases, such as - severe uncontrollable complications (leukemia associated), i.e. sepsis, pneumonia with hypoxia, shock, bleeding at diagnosis - renal insufficiency, if not caused by leukemia - severe impairment of heart or liver function (if not caused by leukemic infiltration) - severe obstructive or restrictive pulmonary disease - known HIV infection or other uncontrolled infections - any other condition that compromises the patient’s eligibility for intensive treatment as described by the study protocol - Late relapse of childhood leukemia or concurrent malignancy

- Previous cytostatic treatment: ALL directed (exceptions: standard prephase, application of steroids 7 days, once-only application of vincristine, cyclophosphamide or other substances as emergency medical intervention); directed to other malignancies within the last 10 years before diagnosis of ALL
- Pregnancy or breastfeeding
- Severe psychiatric disease or any severe concomitant condition under which the patient's understanding of importance and consequences of study participation and/or compliance and therapy according to study protocol cannot be expected
- At diagnosis: participation in another trial that interferes with the antileukemic treatment (exceptions: trials aiming at supportive care, defined accompanying GMALL trials, and at a later timepoint trials with experimental substances, i. e. in case of molecular treatment failure)

Alter	18 - 55 Jahre
Status	Aktiv
Beginn der Rekrutierung	01.08.2016
Fallzahl	900
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Sponsoren	Goethe-Universität Frankfurt am Main (Hauptsponsor)
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Registrierung in anderen Studienregistern	ClinicalTrials.govNCT02881086 European Clinical Trials Database - EUDRACT2013-003466-13