Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

INITIAL-1

Öffentlicher Titel	Phase II Studie zu Inotuzumab Ozogamicin bei älteren Patienten mit akuter lymphatischer Leukämie
Wissenschaftl. Titel	An open label phase II study to evaluate the efficacy and safety of Inotuzumab Ozogamicin for Induction Therapy followed by a conventional chemotherapy based consolidation and maintenance therapy In patients aged 56 years and older with Acute Lymphoblastic leukemia (ALL) (INITIAL-1)
Kurztitel	INITIAL-1
Studiennummer KN/ELN	LN_GMALL_2017_624
Studiengruppe	GMALL
Studienart	multizentrisch, einarmig, prospektiv, offen
Studienphase	Phase II
Erkrankung	Akute lymphatische Leukämie (ALL) - B-Vorläufer ALL
Leukämiestadium	de novo/non-treated
Einschlusskriterien	- Male or female patients, >=56 years of age and fit for therapy - Newly diagnosed acute lymphoblastic leukemia (>25% marrow blasts, assessed by morphology; i.e. M3 marrow) - Leukemic blasts must have CD22 surface expression of a least 20%, assessed by local/institutional flow cytometry of a bone marrow aspirate sample (assessment of CD22 via the reference lab for immungenetics is strongly recommended). In the case of an inadequate aspirate sample (dry tap), flow cytometry of peripheral blood specimen may be substituted if the patient has circulating blasts; alternatively, CD22 expression may be documented by immunohistochemistry of a bone marrow biopsy specimen - No previous ALL-specific treatment with the exception of corticosteroids and/or single dose vincristine and/or a maximum of three doses of cyclophosphamide (cumulative dose of 600mg/m^2) and the standard prephase treatment - With or without documented CNS involvement - Adequate liver function, including total serum bilirubin <2.0 x ULN unless the patient has documented Gilbert syndrome, and aspartate and alanine aminotransferase (AST and ALT) <2.5 x ULN If organ function abnormalities are considered due to leukemic infiltration of the liver, total serum bilirubin must be < 2.5 x ULN and AST/ALT <5 x ULN - Serum creatinine <1.5 x upper limit of normal (ULN) or any serum creatinine level associated with a measured or calculated creatinine clearance of >40 mL/min - WHO performance status <= 2 - Signed written inform consent - Inclusion in GMALL registry
Ausschlusskriterien	- Philadelphia-chromosome or BCR-ABL positive ALL - Burkitt's or mixed phenotype acute leukemia based on the WHO 2008 criteria - Peripheral absolute lymphoblast count >10,000/müL after pre-phase treatment and before start of study medication - Known systemic vasculitis (e.g. , Wegener's granulomatosis, polyarteritis nodosa, systemic lupus erythematosus), primary or secondary immunodeficiency (such as HIV infection or severe inflammatory disease) - Current or chronic hepatitis B or C infection as evidenced by hepatitis B surface antigen and anti-hepatitis C antibody positivity, respectively, or known seropositivity or human immunodeficiency virus (HIV) - Major surgery within <4 weeks before entry on study

- Unstable or severe uncontrolled medical condition (e.g., unstable cardiac function or unstable pulmonary condition)
- Concurrent active malignancy other than non-melanoma skin cancer, carcinoma in situ of the cervix, or localized prostate cancer that has been definitely treated with radiation or surgery; patients with previous malignancies are eligible provided that they have been disease free for >2 years
- Cardiac function, as measured by left ventricular ejection fraction (LVEF) that is less than 45%, or the presence of New York Heart Association (NYHA) stage III or IV congestive heart failure
- Myocardial infarction <6 months before randomization
- History of clinically significant ventricular arrhythmia, or unexplained syncope not believed to be vasovagal in nature, or chronic bradycardic states such as sinoatrial block or higher degrees of AV block unless a permanent pacemaker has been implanted
- Uncontrolled electrolyte disorders that can confound the effects of a QTc prolonging drug (e.g., hypokalemia, hypocalcemia, hypomagnesemia)
- History of chronic liver disease (e.g., cirrhosis) or suspected alcohol abuse
- History of hepatic veno-occlusive disease (VOD) or sinusoidal obstruction syndrome (SOS)
- Administration of live vaccine <6 weeks before randomization
- Evidence of uncontrolled current serious active infection (including sepsis, bacteremia, fungemia) or patients with a recent history (within 4 months) of deep tissue infections such as fasciitis or osteomyelitis
- Patients who have had a severe allergic reaction or anaphylactic reaction to any humanized monoclonal antibodies or any known hypersensitivity to the active substance or any of its excipients
- Pregnant females; breastfeeding females; males and females of childbearing potential (a woman is considered of childbearing potential (WOCBP) i.e. fertile, following menarche and until becoming post-menopausal unless permanently sterile e.g. after hysterectomy or bilateral ovariectomy. Please refer to chapter 12.4 Contraceptive Requirements.) not using highly effective contraception or not agreeing to continue highly effective contraception for women at least 8 months an for men at least 5 months after the last dose of investigational product
- Participation in other studies involving investigational drug(s) (Phase I-IV) within 4 weeks before study inclusion
- Other severe acute or chronic medical or psychiatric condition or laboratory abnormality that may increase the risk associated with study participation or investigational product administration or may interfere with the interpretation of study results and, in the judgment of the investigator, would make the patient inappropriate for entry into this study.

Alter	>= 56 Jahre
Status	Aktiv
Beginn der Rekrutierung	01.11.2017
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