KURZPROTOKOLL
GMALL-EVOLVE

Öffentlicher Titel	Phase II Studie mit Imatinib, Ponatinib und Blinatumomab bei Ph-positiver ALL
Wissenschaftl. Titel	Randomisierte Studie für Ph+ ALL mit Ponatinib versus Imatinib, gefolgt von Blinatumomab und Chemotherapie versus Indikation für Stammzelltransplantation bei molekularer CR oder Blinatumomab gefolgt von Stammzelltransplantation mit unvollständigem Ansprechen
Kurztitel	GMALL-EVOLVE
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Investigator Initiated Trial (IIT), mehrarmig
Studienphase	Phase II
Erkrankung	Blut: Akute lymphatische Leukämie (ALL): Neu diagnostiziert / de novo

Einschlusskriterien

- Male or female patients >= 18 years, <=65 years
- Philadelphia chromosome or BCR-ABL1 positive ALL
- Not previously treated except with corticosteroids 7 days, standard GMALL prephase with dexamethasone and cyclophosphamide including intrathecal therapy, hydroxyurea, a single dose vincristine or other cytostatic drugs and start of standard induction for Ph-positive ALL (1 dose vincristine, 1 dose of Rituximab, 2 doses dexamethasone and up to 5 days Imatinib)
- ECOG performance status 2
- Signed written inform consent
- Molecular evaluation for BCR-ABL1 performed
- Negative pregnancy test in women of childbearing potential
- Woman of childbearing potential 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 (Pearl-Index <1%). Male who has a female partner of childbearing potential 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 (Pearl-Index <1%).
- Normal serum levels > LLN (lower limit of normal) of potassium and magnesium, or corrected to within normal limits with supplements, prior to the first dose of study medication
- Serum lipase 1.5 x ULN. For serum lipase > ULN - 1.5 x ULN, value must be considered not clinically significant and not associated with risk factors for acute pancreatitis
- Normal QTcF interval 450 ms for males and 470 ms for females
- Signed and dated written informed consent is available
- Participation in the registry of the German Multicenter Study Group for Adult ALL (GMALL)

Ausschlusskriterien

- History of malignancy other than ALL diagnosed within 5 years (yrs) prior to start of protocol-specified therapy with defined exceptions
- Contraindications against the use of Imatinib, Ponatinib, chemotherapy or Blinatumomab
- Patient previously treated with tyrosine kinase inhibitors
- Nursing women
- Known impaired cardiac function, including any of the following: as detailed in protocol
- Symptomatic peripheral vascular disease
- Any history of ischemic stroke or transient ischemic attacks (TIAs)
- Uncontrolled hypertriglyceridaemia

- History or presence of clinically relevant CNS pathology as detailed in protocol
- History or active relevant autoimmune disease
- Known hypersensitivity to immunoglobulins or to any other component of the study drug formulation
- Known diagnosis of human immunodeficiency virus (HIV) infection (HIV testing is not mandatory) or active infection with Hepatitis B or C
- History of pancreatitis within 6 months previous to start of treatment within the trial
- Treatment with any other investigational agent or participating in another trial within 30 days prior to entering this study
- Inadequate hepatic functions defined as ASAT or ALAT > 2,5 times the institutional upper limit of normal or > 5 times ULN if considered due to leukemia
- Total bilirubin > 1.5-fold the institutional upper limit unless considered to be due to organ involvement by the leukemia or to M. Gilbert / M. Meulengracht
- Concurrent severe diseases which exclude the administration of therapy e.g. severe, uncontrolled acute or chronic infections
- Inability to understand and/or unwillingness to sign a written informed consent

Alter

18 - 65 Jahre

Prüfzentren

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Sponsor

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Förderer

Bundesministerium für Bildung und Forschung

Registrierung in anderen Studienregistern

ClinicalTrials.gov NCT06061094
EudraCT 2022-000760-21

Links

Zu den Ein- und Ausschlusskriterien

Studiendokumente zum Download (roXtra)