

Öffentlicher Titel	Dasatinib in patients with newly diagnosed Core-Binding Factor AML
Wissenschaftl. Titel	Randomized Phase III Study of Intensive Chemotherapy with or without Dasatinib (Sprycel™) in Adult Patients with Newly Diagnosed Core-Binding Factor Acute Myeloid Leukemia (CBF-AML)
Kurztitel	AMLSG 21-13
Studiennummer KN/ELN	LN_AMLSGU_2014_550
Studiengruppe	AMLSG Ulm
Studienart	multizentrisch, randomisiert, prospektiv, offen, zweiarmig
Studienphase	Phase III
Erkrankung	Akute myeloische Leukämie (AML) - AML alle außer FAB M3
Leukämiestadium	de novo/non-treated - Genotyp-spezifische Therapiekonzepte - Alle Altersgruppen
Molekularer Marker	CBF
Ziele	<ul style="list-style-type: none"> - To assess event-free survival (EFS) after intensive induction (daunorubicin and cytarabine) and consolidation (high-dose cytarabine) chemotherapy with or without dasatinib in patients with CBF-AML - To assess the interaction between type of CBF-AML [t(8;21) versus inv(16)] and randomization accordingly on all survival endpoints - To assess cumulative incidence of relapse (CIR) and death (CID) - To assess relapse-free (RFS) and overall survival (OS) - To assess outcome according to KIT mutational status - To assess pharmacodynamic inhibition of KIT - To assess toxicity
Einschlusskriterien	<ul style="list-style-type: none"> - Both female and male patients meeting the inclusion and exclusion criteria will be included in this clinical trial, because the acquisition of an AML is independent of gender. Patients must meet all of the following inclusion criteria to be eligible for enrollment into the study - Core-binding factor (CBF) AML with molecular diagnosis of RUNX1-RUNX1T1 fusion transcript resulting from t(8;21)(q22;q22) (or a variant form) or of CBF-MYH11 fusion transcript resulting from inv(16)(p13.1q22)/t(16;16)(p13.1;q22) as assessed in one of the two central AMLSG reference laboratories. - Age \geq 18; there is no upper age limit - No prior chemotherapy for leukemia except hydroxyurea to control hyperleukocytosis if needed for up to 5 days during the diagnostic screening phase. - Non-pregnant and non-nursing. Due to the unknown teratogenic potential of dasatinib in humans, pregnant or nursing patients may not be enrolled. Women of childbearing potential (WOCBP) must have a negative serum or urine pregnancy test within a sensitivity of at least 25 mIU/mL within 72 hours prior to registration. Women of childbearing potential must either commit to continued abstinence from heterosexual intercourse or begin TWO acceptable methods of birth control - one highly effective method (e.g., IUD, hormonal, tubal ligation, or partner's vasectomy), and one additional effective method (e.g., latex condom, diaphragm, or cervical cap) - AT THE SAME TIME, at least four weeks before she begins dasatinib therapy and at least 3 months after last dasatinib administration. "Women of childbearing potential" is defined as a sexually active mature woman who has not undergone a hysterectomy or who has had menses at any time in the preceding 24 consecutive months. - Men must agree not to father a child and must use a latex condom during any sexual contact with women of childbearing potential while taking dasatinib and for 3 months after therapy is stopped, even if they have undergone a successful vasectomy. - Signed written informed consent.

Ausschlusskriterien

- Performance status WHO >2
- Pulmonary edema and/or pleural/pericardial effusion within 14 days of Day 1. If edema/effusion resolves to CTC Grade ≤ 1, patients can be treated with dasatinib.
- Patients with ejection fraction < 50% by MUGA or ECHO scan within 14 days of day 1
- Organ insufficiency (creatinine >1.5x upper normal serum level; bilirubin, AST or AP >2.5x upper normal serum level; heart failure NYHA III/IV; severe obstructive or restrictive ventilation disorder)
- Uncontrolled infection
- Severe neurological or psychiatric disorder interfering with ability of giving an informed consent
- Patients with a "currently active" second malignancy other than non-melanoma skin cancers. Patients are not considered to have a "currently active" malignancy if they have completed therapy and are considered by their physician to be at less than 30% risk of relapse within one year.
- Known positive for HIV, active HBV, HCV, or Hepatitis A infection
- Bleeding disorder independent of leukemia
- No consent for registration, storage and processing of the individual disease-characteristics and course as well as information of the family physician and/or other physicians involved in the treatment of the patient about study participation.
- No consent for biobanking.

Alter	Alle Altersgruppen
Status	Aktiv
Beginn der Rekrutierung	22.07.2014
Fallzahl	277
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Sponsoren

Universitätsklinikum Ulm

Förderer

Universitätsklinikum Ulm

Bristol-Myers Squibb

**Registrierung in anderen
Studienregistern**

ClinicalTrials.govNCT02013648