

## **KURZPROTOKOLL** **AMLSG 21-13**

<b>Öffentlicher Titel</b>	Dasatinib bei Patienten mit neu diagnostizierter Core-Binding Factor AML
<b>Wissenschaftl. Titel</b>	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)
<b>Kurztitel</b>	AMLSG 21-13
<b>Studienart</b>	multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
<b>Ziele</b>	<ul style="list-style-type: none"><li>- 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</li><li>- To assess the interaction between type of CBF-AML [t(8;21) versus inv(16)] and randomization accordingly on all survival endpoints</li><li>- To assess cumulative incidence of relapse (CIR) and death (CID)</li><li>- To assess relapse-free (RFS) and overall survival (OS)</li><li>- To assess outcome according to KIT mutational status</li><li>- To assess pharmacodynamic inhibition of KIT</li><li>- To assess toxicity</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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 CBFB-MYH11 fusion transcript resulting from inv(16)(p13.1q22)/t(16;16)(p13.1;q22) as assessed in one of the central AMLSG reference laboratories (Ulm, Hannover)</li><li>- Age 18; there is no upper age limit</li><li>- No prior chemotherapy for leukemia except hydroxyurea for up to 5 days during the diagnostic screening phase</li><li>- 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.</li><li>- 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.</li><li>- Signed written informed consent.</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Performance status WHO &gt;2</li><li>- 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.</li><li>- Patients with ejection fraction &lt;50% by echocardiography within 14 days of day 1</li><li>- Organ insufficiency (creatinine &gt;1.5x upper normal serum level; bilirubin, AST or AP &gt;2.5x upper normal serum level; heart failure NYHA III/IV; severe obstructive or restrictive ventilation disorder)</li><li>- Uncontrolled infection</li></ul>

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- 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.
- Severe neurological or psychiatric disorder interfering with ability of giving an informed consent
- 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**

18 Jahre und älter

**Prüfzentren**

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**Sponsor**

Universität Ulm

**Registrierung in anderen  
Studienregistern**

ClinicalTrials.gov NCT02013648 (primäres Register)  
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