KURZPROTOKOLL
MIDOKIT

Öffentlicher Titel	Midostaurin und Standardchemotherapie bei KIT- oder FLT3-ITD positiver t(8;21) AML
Wissenschaftl. Titel	A single-arm phase II trial to assess the efficacy of midostaurin (PKC412) added to standard primary therapy in patients with newly diagnosed c-KIT or FLT3-ITD mutated t(8;21)AML
Kurztitel	MIDOKIT
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig
Studienphase	Phase II
Erkrankung	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
Ziele	- To compare CR, OS, and CIR rates in the two arms - To compare the toxicity profile in the two arms - To compare the kinetics of MRD in the two arms - To compare the duration of patient hospitalization in the two arms - To compare the QoL between the two arms - To compare the event free survival rates in the two arms in the whole population
Einschlusskriterien	- Signed written informed consent according to IGH/EU/GCP and national local laws - Newly diagnosed APL confirmed by the presence of t (15;17) or PML/RAR by RT-PCR or micro speckled PML nuclear distribution in leukemic cells - Age >=18 and <71 years - WHO performance status 0-2 included - Serum total bilirubin <=3.0 mg/dl - Serum creatinine <=3.0 mg/dl - WBC at diagnosis <= 10x10^9 /L
Ausschlusskriterien	- Age <18 and >=71 - WBC > 10x10^9 /L - Active malignancy at time of study entry - Lack of diagnostic confirmation at genetic level - Significant arrhythmias, EKG abnormalities or neuropathy - Cardiac contraindications for intensive chemotherapy (L-EF < 50%) - Uncontrolled, life-threatening infections - Severe uncontrolled pulmonary or cardiac disease - Women who are either pregnant or breast feeding, or of child-bearing potential, defined as all women physiologically capable of becoming pregnant, UNLESS they meet on eof the following definitions: Amenorrhea, post surgical bilateral oophorectomy with or without hysterectomy Using a highly effective method of birth control (defined as those which result in a failure rate less than 1 % per year) when used consistently an d correctly such as implants, injectables, oral contraceptives, IUDs, sexual abstinence or vasectomized partner - Concomitant severe psychiatric disorder - HIV positivity - Use of other investigational drugs at the time of enrolment or within 30 days before study entry
Alter	18 - 70 Jahre
Molekularer Marker	FLT3 AML-ETO KIT
Fallzahl	1

Prüfzentren	**Universitätsmedizin Frankfurt** (Rekrutierung beendet) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Sabine Hug Tel: 069 6301-6353 Fax: 069 6301-7463 s.hug@em.uni-frankfurt.de
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01830361 EudraCT 2011-002567-17