Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

AMLSG 23-14

Öffentlicher Titel	Phase I/II Studie zu Palbociclib in MLL-rearranged akuten Leukämien
Wissenschaftl. Titel	Phase Ib/IIa study of palbociclib in MLL-rearranged acute leukemias AMLSG 23-14/Palbo-AL-1
Kurztitel	AMLSG 23-14
Studiennummer KN/ELN	LN_AMLSGU_2015_571
Studiengruppe	AMLSG Ulm
Studienart	multizentrisch, einarmig, prospektiv, offen
Studienphase	Phase I/II
Erkrankung	Akute myeloische Leukämie (AML) - AML alle außer FAB M3
Leukämiestadium	de novo/non-treated - Genotyp-spezifische Therapiekonzepte - Alle Altersgruppen
Molekularer Marker	MLL-rearranged
Ziele	- Phase Ib: Safety of palbociclib in patients with MLL-rearranged leukemia; Tolerability of palbociclib in patients with MLL-rearranged leukemia - Phase IIa: Overall response rate including CR, Cri, PR & ALE of patients with MLL-rearranged leukemia treated with palbociclib
Einschlusskriterien	- Both female and male patients meeting the inclusion and exclusion criteria will be included in this clinical trial as the occurrence of acute leukemia is independent of gender. Patients must meet all of the following inclusion criteria to be eligible for enrollment into the study: - 1. Patients with confirmed diagnosis of acute leukemia with MLL rearrangement according to the 2008 WHO Classification - 2. Patients with MLL-rearranged leukemia who are refractory to standard induction therapy and not immediate candidates for allogeneic HSCT (bridge to transplant is allowed) - 3. Patients with MLL-rearranged leukemia who relapsed after standard first-line treatment and are not immediate candidates for allogeneic HSCT (bridge to transplant is allowed) - 4. Patients with newly diagnosed MLL-rearranged leukemia who are not eligible for intensive first-line therapy - 5. Genetic assessment in the AMLSG central laboratory - 6. Age 18 years, no upper age limit - 7. WHO performance status of 2 - 8. No prior chemotherapy two weeks before study entry except hydroxyurea to control hyperleukocytosis - 9. Non-pregnant and non-nursing. Women of child-bearing potential must have a negative serum or urine pregnancy test with a sensitivity of at least 25 mIU/mL within 72 hours prior to registration (WOCBP 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 months). - 10. Female patients in the reproductive age and male patients must agree to avoid getting pregnant or to father a child while on therapy and for three months after the last dose of therapy. - 11. Women of child-bearing potential must either commit to continued abstinence from heterosexual intercourse or begin one acceptable method of birth control (IUD, tubal ligation, or partner’s vasectomy). Hormonal contraception is an inadequate method of birth control. - 12. Men must agree not to father a child and must use a latex condom during any sexual contact with WOCBP while receiving therapy and for three months after therapy is stopped, even if they have undergone successful vasectomy.

	- 13. Signed written informed consent
Ausschlusskriterien	- Prior treatment with palbociclib - Performance status > 2 according to WHO criteria - Organ insufficiency: creatinine > 1.5 x upper normal serum level; bilirubin, AST, or AP > 2.5 x upper normal serum level; heart failure NYHA III/IV; uncontrolled hypertension; unstable angina; serious cardiac arrhythmia; severe obstructive or restrictive ventilation disorder - Uncontrolled infection - Patients with a “currently active” second malignancy other than non-melanoma skin cancer. 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 neurologic or psychiatric disorder interfering with ability of giving informed consent - Known or suspected active alcohol or drug abuse - Known positivity for HIV, active HAV, HBV, or HCV infection - Bleeding disorder unrelated to leukemia - Uncontrolled CNS involvement (treatment for CNS-involvement prior to inclusion is allowed) - QTc > 470 msec (based on the mean value of triplicate ECGs), family or personal history of long or short QT syndrome, Brugada syndrome, or known history of QTc prolongation or Torsade de Pointes - Uncontrolled electrolyte disorders that can aggravate the effects of a QTc-prolonging drug (e.g., hypocalcemia, hypokalemia, hypomagnesemia) - No consent for registration, storage, and processing of individual disease characteristics, information on the course of the disease, and information obtained from the family physician and/or other physicians involved in the treatment of the patient about study participation - No consent for biobanking
Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	01.08.2015
Rekrutierende Länder	Deutschland
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Labore / Zentrale Diagnostik	**MLL Diagnostik** Labor für Zytogenetische und Molekulargenetische Diagnostik, Klinik für Innere Med. III, Universitätsklinikum Ulm
Sponsoren	Universitätsklinikum Ulm
Förderer	Universitätsklinikum Ulm Pfizer
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT02310243