Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

DASPERSE (CA180-400)

Öffentlicher Titel	Dasatinib bei CP-CML und chronischer Toxizität gegenüber Imatinib
Wissenschaftl. Titel	A Phase IV, Open-label, Multicenter Study of Dasatinib in Chronic-Phase Chronic Myeloid Leukemia (CP-CML) Patients With Chronic, Low-grade Non-Hematologic Toxicity to Imatinib
Kurztitel	DASPERSE (CA180-400)
Studiennummer KN/ELN	LN_NN_2013_539
Studiengruppe	NN
Studienart	multizentrisch, offen
Studienphase	Phase IV
Erkrankung	Chronische myeloische Leukämie (CML) - Chronische Phase
Leukämiestadium	TKI-Resistenz, -intoleranz
Haupt- und Nebenzielkriterien	- Frequency of reduction in grade (Grade 2 to 1) or resolution of imatinib-related chronic Grade 1 or Grade 2 non-hematologic AEs at 3 months after switch to dasatinib 3 months after switch to dasatinib (Hauptzielkriterium) - Change in patient reported CML symptom severity by Mean change in M.D. Anderson Symptom Inventory- Chronic Myeloid Leukemia (MDASI-CML) score 3, 6, 12 months - Change in patient reported quality of life measured by EORTC-Quality of Life Questionnaire score 6, 12 months - Frequency of dasatinib-related adverse events 12 months - Proportion of patients with reduction or improvement of at least 1 imatinib-related Grade 1 or Grade 2 chronic AE, without a worsening of any imatinib-related, chronic adverse events 3 months - Rate of major molecular response 6, 12 months
Einschlusskriterien	- signed Informed - Subjects with CP-CML achieving an optimal response (either CHR by 3 months, PCyR by 6 months, or CCyR by 12 months) to imatinib <= 400 mg/day treatment - Currently experiencing at least one imatinib-related Grade 1 or 2 non-hematologic adverse event persisting for at least 2 months or recurring at least 3 times in the preceding 12 months, despite best supportive care - Daily ECOG performance status = 0 – 2 - Life expectancy >6 months - Adequate renal function defined as serum creatinine <= 3 times the institutional ULN - Adequate hepatic function defined as: total bilirubin <= 3.0 times the institutional ULN; alanine aminotransferase (ALT) and aspartate aminotransferase (AST) <= 5.0 times the institutional upper limit of normal (ULN) - Serum Na, K, Mg, and total serum Ca or ionized Ca levels must be greater than or equal to the institutional lower limit of normal. Subjects with low K, Mg levels, total serum Ca and/or ionized Ca must be repleted to allow for protocol entry. - Men and women, ages 18 or older - Women of childbearing potential (WOCBP) must use highly effective methods of birth control to minimize the risk of pregnancy. WOCBP must follow instructions for birth control for the entire duration of the study including a minimum of 1 month (4 weeks) after dosing has been completed. Acceptable methods of highly effective birth control include: Condom with spermicide, Diaphragm and spermicide, Cervical cap and spermicide; the use of intrauterine devices, (IUDs) shall be at the discretion of the investigator

- Women must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of HCG) within 72 hours prior to the start of investigational product
- Women must not be breastfeeding
- Sexually active fertile men must use highly effective birth control if their partners are WOCBP. Men that are sexually active with WOCBP must follow instructions for birth control for the entire duration of the study and a minimum of 1 month (4 weeks) after dosing has been completed

Ausschlusskriterien

- Previous treatment with any other TKI, except imatinib
- Current Grade 3 or 4 imatinib-related adverse event
- Subjects with clonal evolution in Ph+ cells observed in >= 2 metaphases at baseline bone marrow (BM) cytogenetic test, unless the same abnormalities were present at diagnosis
- Subjects with previous loss of CHR or loss of major cytogenetic response (MCyR) on imatinib
- Previous diagnosis of accelerated or blast phase CML
- A serious uncontrolled medical disorder or active infection that would impair the ability of the subject to receive protocol therapy
- Uncontrolled or significant cardiovascular disease, including any of the following: i. Congestive cardiac failure (NYHA > 2) within 3 months, ii. Diagnosed or suspected congenital long QT syndrome, iii. Any history of clinically significant ventricular arrhythmias, iv. Prolonged QTcF interval on pre-entry electrocardiogram (> 450 msec), v. Any history of second or third degree heart block (may be eligible if the subject currently has a pacemaker), vi. Uncontrolled angina within 3 months, vii. Prior myocardial infarction within 6 months, viii. Uncontrolled hypertension
- Known pulmonary arterial hypertension
- Pleural or pericardial effusions of any grade at study entry are excluded. Subjects previously diagnosed with pleural/pericardial effusion of any grade resolved at the time of study entry are allowed
- History of significant bleeding disorder unrelated to CML, including i. Diagnosed congenital bleeding disorders (eg, von Willebrand's disease), ii. Diagnosed acquired bleeding disorder within one year (eg, acquired antifactor VIII antibodies)
- Serious mental illness interfering with the ability to participate in the study
- Prior documented T315I mutation (Enrollment is not dependent upon results of baseline mutation analysis)
- Patients who are pregnant or breastfeeding or likely to become pregnant
- Men whose partner is unwilling or unable to avoid pregnancy
- Prisoners or subjects who are involuntarily incarcerated
- Subjects who are compulsorily detained for treatment of either a psychiatric or physical (eg, infectious disease) illness
- Subjects unable to complete patient-reported outcomes without assistance

Alter >= 18 Jahre

Status Geschlossen

Beginn der Rekrutierung 01.09.2013

Fallzahl 75

Studienleiter/in
Hochhaus, Prof. Dr. med., Andreas
Universitätsklinikum Jena
Klinik und Poliklinik für Innere Medizin II
Erlanger Allee 101
07740 Jena
Tel: +49 (0)3641 932 4201
Fax: +49 (0)3641 932 4202
E-Mail: andreas.hochhaus@med.uni-jena.de

Sponsoren	Bristol-Myers Squibb (Hauptsponsor)
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT01660906 European Clinical Trials Database - EUDRACT2011-006180-21