Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

AMLSG 26-16 / AML-ViVA

Öffentlicher Titel	Phase II Studie mit niedrig-dosiertem Azacitidine, ATRA und Pioglitazon bei älteren Patienten mir refraktärer AML
Wissenschaftl. Titel	Randomisierte Phase II Studie mit Sicherheits Run-in Phase zur Evaluation von niedrig-dosiertem Azacitidin, All-trans Retinsäure und Pioglitazon im Vergleich zu standard-dosiertem Azacitidin in Patienten (60 Jahre oder älter) mit akuter myeloischer Leukämie (AML), die refraktär ist auf Standardinduktionschemotherapie.
Kurztitel	AMLSG 26-16 / AML-ViVA
Studiennummer KN/ELN	LN_AMLSGU_2017_614
Studiengruppe	AMLSG Ulm
Studienart	multizentrisch, randomisiert, prospektiv, offen, zweiarmig
Studienphase	Phase II
Erkrankung	Akute myeloische Leukämie (AML) - AML alle außer FAB M3
Leukämiestadium	rezidiviert/refraktär
Ziele	- To evaluate efficacy (overall survival) and safety of low-dose Azacitidine, ATRA and Pioglitazone in comparison to standard dose Azacitidine
Einschlusskriterien	- Patients with confirmed diagnosis of acute myeloid leukemia (AML) who are refractory (no CR, no CRi, no PR) to at least one cycle of intensive induction therapy and not eligible for further intensive induction therapy based on documented medical reasons (e.g. disease characteristics or patient characteristics), or - Patients with confirmed diagnosis of acute myeloid leukemia (AML) who are refractory (no CR, no CRi, no PR) to at least one cycle of intensive induction therapy and not immediate candidates for allogeneic HSCT (bridge to transplant is allowed) - Age 60 or older, no upper age limit - ECOG performance status of <= 2 at screening - To control hyperleukocytosis or extramedullary involvement, medication with hydroxyurea is allowed up to 24h before start of study treatment. In case of hyperleukocytosis hydroxyurea should be given and start of study treatment should be delayed until leukocyte counts are <= 15 x 10^9/L
Ausschlusskriterien	- Known or suspected hypersensitivity to the study drugs and/or any excipients - Patients with acute promyelocytic leukemia exhibiting t(15;17)(q22;q12); PML-RARA, or with variant translocations - Acute myeloid leukemia (AML) with isocitratdehydrogenase (IDH) 1 or 2 mutations if results are available from the central AMLSG reference laboratories - ECOG performance status > 2 - Inadequate cardiac, hepatic and/or renal function at Screening Visit defined as: (a) heart failure NYHA II-IV; (b) unstable angina pectoris; (c) total bilirubin, ALT, AST > 2.5 x upper normal serum level; (d) Creatinine > 1.5 x upper normal serum level - Active central nervous system involvement - Patients with a “currently active” second malignancy requiring active therapy other than non-melanoma skin cancers (except for hormonal/antihormonal treatment, e.g. in prostate or breast cancer) - Patients with “currently active” bladder cancer or bladder cancer in their history, patients with risk factors for bladder cancer (e.g. exposure to aromatic amines or heavy tobacco smoker), or macrohematuria of unknown origin - Treatment with any other clinical study drug within 14 days before the first administration of the investigational drugs or at any time during the
Alter	>= 60 Jahre
Status	Aktiv
Beginn der Rekrutierung	31.05.2017

Fallzahl	94
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Förderer	Celgene Anticancer Fund
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT02942758