Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

RELAZA2

Öffentlicher Titel	Azacitidin bei drohendem hämatologischen Rezidiv
Wissenschaftl. Titel	Treatment of Patients With MDS or AML With an Impending Hematological Relapse With Azacitidin (Vidaza)
Kurztitel	RELAZA2
Studiennummer KN/ELN	LN_SAL_2011_487
Studiengruppe	SAL
Studienphase	Phase II
Erkrankung	Myelodysplastisches Syndrom (MDS) - Intermediär II und Hochrisiko Akute myeloische Leukämie (AML) - AML alle außer FAB M3
Leukämiestadium	molekulares Rezidiv
Molekularer Marker	NPM1
Ziele	- Analysis of the effectiveness of azacitidine 6 months after start of therapy to prevent a hematological relapse in MDS or AML patients with significant residuals or an increase of minimal residual disease (MRD) which is defined as - decrease of CD34 donor chimerism (<80%) after allogeneic related or unrelated HSCT in CD34+ MDS or AML or - increase in the AML-specific molecular markers in the quantitative PCR for t(8,21), inv16, t(6,9), NPM1+ AML >1% (ratio to reference gene) after conventional chemotherapy or allogeneic HSCT or - persistence of the (above) MRD level >1% after conventional chemotherapy or alloge -neic HSCT - tolerance of azacitidine - quality of the response of the MRD (major vs. minor) and the relapse-free survival and overall survival 12, 24 and 30 months after starting treatment with azacitidine - modulation of CD34+, NK- and T-cells of MDS and AML patients by azacitidine
Haupt- und Nebenzielkriterien	- Number of patients with hematological relapse 6 months after start of treatment with azacitidin 6 months after end of treatment (Hauptzielkriterium) - Number of occurrence or exacerbation of clinical relevant acute or chronic GvHD 2 years follow-up after treatment - Number of patients with infectious SAEs (rate of SAE) 2 years follow-up after treatment - Rate of changes of methylation in CD34+ cells 2 years follow-up after treatment - Relapse-free survival and overall survival 12, 24 and 30 months after start of treatment
Einschlusskriterien	- Screening: - signed informed consent - Age >=18 years - patients with MDS or AML after conventional chemotherapy or allogeneic HSCT and positive molecular marker such as t(8,21), inv16, t(6,9), NPM1 pos. or CD34+ in the case of an allogeneic HSCT - Treatment: - MDS or AML without haematological relapse (blasts < 5 % in the bone marrow), and - decrease of CD34 donor chimerism (< 80 %) after allogeneic related or unrelated HSCT in CD34+ MDS or AML or - increase in the AML-specific molecular marker in the quantitative PCR for t(8;21), inv16, t(6,9), NPM1+ AML >1% after conventional chemotherapy or allogeneic HSCT or

- persistence of the (above) MRD levels > 1 % (relative to the reference gene) after conventional chemotherapy or allogeneic HSCT
- leukocytes > 3 Gpt/l and platelets > 75 Gpt/l (transfusion independent)

Ausschlusskriterien

- Known history of hypersensitivity to any of the drugs used or their constituents or to drugs with similar chemical structure,
- Participation of the patient in another clinical trial within the last 4 weeks before the inclusion
- addiction or other disorders that do not allow the concerned person, to assess the nature and scope and possible consequences in the clinical investigation
- pregnant or breast feeding women
- women of childbearing potential, except women who meet the following criteria:
- post-menopausal (12 months natural amenorrhea or 6 months amenorrhea with serum FSH >40 U/ml)
- postoperative (6 weeks after bilateral ovariectomy with or without hysterectomy)
- regular and proper use of a contraceptive method with error rate < 1 % per year (e.g., implants, depot injections, oral contraceptives, intrauterine device, IUD)
- sexual abstinence
- Vasectomy of the partner
- Men who do not use one of the following types of contraception for a period of 3 months after completion of therapy:
- sexual abstinence
- State post-vasectomy
- Condom
- Evidence that the participating person is not expected to comply with the protocol (such as lack of cooperation)
- Uncontrolled active infection
- Severe hepatic impairment (AST and ALT may not exceed three times the normal) or liver cirrhosis or malignant liver tumor
- Dialysis dependent renal dysfunction
- Known severe congestive heart failure, incidence of clinically unstable cardiac or pulmonary disease These criteria are not for the screening phase up to a known allergic reaction to azacitidine or intolerance to apply.

Alter >= 18 Jahre

Status Aktiv

Beginn der Rekrutierung 28.09.2011

Rekrutierende Länder Deutschland

Studienleiter/in

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Sponsoren	Technische Universität Dresden (Hauptsponsor)
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT01462578 (primäres Register)
Therapie	Drug: Azacitidine injection, subcutaneous; initial minimum 6 cycles; another 6 or 12 cycles according to MRD niveau; maximum 24 cycles
Anmerkung	Teilnehmende Prüfzentren: Charité Campus Benjamin Franklin, Universitätsmedizin Berlin; Universitätsklinikum Carl Gustav Carus, Medizinische Klinik und Poliklinik I, Dresden; Universitätsklinikum Essen, Klinik für Hämatologie (Westdeutsches Tumorzentrum); Universitätsklinikum Frankfurt, Medizinische Klinik II, Hämatologie/Onkologie; Klinikum rechts der Isar der, TU München; Universitätsklinikum Münster, Medizinische Klinik und Poliklinik A; Ruprecht-Karls-Universität Heidelberg, Medizinische Klinik V; Universitätsklinikum Freiburg, Klinik für Innere Medizin I; Klinikum der Universität München, Campus Großhadern; www.sal-aml.org