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Trial record **1 of 1** for: NCT01462578

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Treatment of Patients With Myelodysplastic Syndrome or Acute Myelocytic Leukemia With an Impending Hematological Relapse With Azacitidine (Vidaza) (RELAZA2)

This study is currently recruiting participants.

Verified December 2013 by Technische Universität Dresden

Sponsor:
Technische Universität Dresden

Information provided by (Responsible Party):
Technische Universität Dresden

ClinicalTrials.gov Identifier:
NCT01462578

First received: June 22, 2011
Last updated: December 17, 2013
Last verified: December 2013
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

Assessment of efficacy of azacitidine to prevent a relapse

Condition	Intervention	Phase
Acute Myelocytic Leukemia Myelodysplastic Syndrome	Drug: Azacitidine	Phase 2

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment
Official Title:	Treatment of Patients With MDS or AML With an Impending Hematological Relapse With Azacitidine (Vidaza)

Resource links provided by NLM:

Genetics Home Reference related topics: core binding factor acute myeloid leukemia cytogenetically normal acute myeloid leukemia familial acute myeloid leukemia with mutated CEBPA

MedlinePlus related topics: Acute Myeloid Leukemia Cancer Leukemia Myelodysplastic Syndromes

Drug Information available for: Azacitidine

Genetic and Rare Diseases Information Center resources: Leukemia, Myeloid Myelodysplastic Syndromes Acute Myelocytic Leukemia Acute Non Lymphoblastic Leukemia

U.S. FDA Resources

Further study details as provided by Technische Universität Dresden:

Primary Outcome Measures:

- Number of patients with hematological relapse 6 months after start of treatment with azacitidin [Time Frame: 6 months after end of treatment] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Number of occurrence or exacerbation of clinical relevant acute or chronic GvHD [Time Frame: 2 years follow-up after treatment] [Designated as safety issue: No]
- Number of patients with infectious SAEs (rate of SAE) [Time Frame: 2 years follow-up after treatment] [Designated as safety issue: Yes]
- Rate of changes of methylation in CD34+ cells [Time Frame: 2 years follow-up after treatment] [Designated as safety issue: No]
- Relapse-free survival and overall survival [Time Frame: 12, 24 and 30 months after start of treatment] [Designated as safety issue: Yes]

Relapse-free survival and overall survival 12, 24 and 30 months after start of treatment

Estimated Enrollment:	53
Study Start Date:	September 2011
Estimated Study Completion Date:	October 2017
Estimated Primary Completion Date:	January 2015 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Azacytidine injection: 75 mg/m²/d, subcutaneous	Drug: Azacitidine injection: 75 mg/m²/d, subcutaneous; initial minimum 6 cycles; another 6 or 12 cycles according to MRD niveau; maximum 24 cycles Other Name: Vidaza®

Detailed Description:
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+ or CD117+ 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 allogeneic 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

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

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+ or CD117+ 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+ or CD117+ 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)

Exclusion Criteria:

- 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.

Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01462578

Contacts

Contact: Uwe Platzbecker, Prof. Dr. med. Uwe.Platzbecker@uniklinikum-dresden.de

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Locations

Germany

Charité Campus Benjamin Franklin **Recruiting**
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Klinikum Chemnitz (Küchwald) **Recruiting**
Chemnitz, Germany
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Universitätsklinikum Carl Gustav Carus, Medizinische Klinik und Poliklinik I **Recruiting**
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Principal Investigator: Uwe Platzbecker, Prof. Dr. med.

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Universitätsklinikum Heidelberg, Medizinische Klinik, Abt. Innere Medizin V — **Recruiting**
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Klinikum rechts der Isar der TU München, III. Med. Klinik und Poliklinik — **Recruiting**
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Principal Investigator: Matthias Stelljes, Prof. Dr. med.

Sponsors and Collaborators

Technische Universität Dresden

Investigators

Principal Investigator: Uwe Platzbecker, Prof. Dr. med. Universitätsklinikum Carl Gustav Carus, Medizinische Klinik und Poliklinik I, 01307 Dresden

More Information

Additional Information:

Website Study Alliance Leukemia (coordinating study group) EXIT

No publications provided

Responsible Party:	Technische Universität Dresden
ClinicalTrials.gov Identifier:	NCT01462578 History of Changes
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Health Authority:	Germany: Federal Institute for Drugs and Medical Devices

Keywords provided by Technische Universität Dresden:
Neoplasms benign, malignant and unspecified
Acute myeloid leukemia
AML
Myelodysplastic syndrome
MDS

Additional relevant MeSH terms:

Leukemia	Precancerous Conditions
Leukemia, Myeloid, Acute	Azacitidine
Leukemia, Myeloid	Antimetabolites, Antineoplastic
Myelodysplastic Syndromes	Antimetabolites
Preleukemia	Molecular Mechanisms of Pharmacological Action
Neoplasms by Histologic Type	Pharmacologic Actions
Neoplasms	Antineoplastic Agents
Bone Marrow Diseases	Therapeutic Uses
Hematologic Diseases	Enzyme Inhibitors

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