Decitabine-cytarabine chemotherapy in elderly AML and high risk MDS patients (> 65 years) with high early mortality risk

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23606

Source
NTR

Brief title
Decitabine-cytarabine

Health condition

Acute myeloid leukemia (AML), Myelodysplasia (MDS), Acute myeloide leukemie, Myelodysplasie, Chemotherapy, Chemotherapie

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

Mortality at day 30 after start of decitabine-cytarabine chemotherapy

Secondary outcome

Remission status after one and two cycles of decitabine-cytarabine

Study description

Background summary

This is a phase 1-2 study to determine feasiblity and safety of decitabine-cytarabine chemotherapy in patients > 65 years with AML or high risk MDS, who have a high risk for day 30 mortality during standard treatment with intensive chemotherapy bcause of the presence of co-morbidity (HCT-CI >=2).

Study objective

In this study we explore the feasibility of combined decitabine and cytarabine chemotherapy in AML and high risk MDS patients with a high risk of early mortality (day 30 mortality) during standard induction chemotherapy (HCT-CI co-morbidity index >=2). With the decitabine-cytarabine chemotherapy we hope to achieve a low incidence of early mortality. At the same time we hope to achieve complete remissions in the majority of patients.

Study design

1. Day 30 after start of decitabine-cytarabine chemotherapy

2. Four weeks after discharge from the second cycle of decitabine-cytarabine (end of study)

Intervention

Patients will receive decitabine one time daily 20 mg/m2 during 5 days, directly followed by cytarabine 100 mg/m2 per day as continuous infusion during 5 days. At day 28-35 after the start of chemotherapy, remission status will be determined. In case of CR, CRi or morphologic leukemia-free state, patients will receive a second cycle of decitabine-cytarabine.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with AML or high risk MDS (IPSS-R ¡Ý 4.5)

2. > 65 years

3. WHO performance score 0-2

4. HCT-CI score >=2

5. Written informed consent

Exclusion criteria

1. Previous treatment with decitabine, azacitidine or intensive chemotherapy for this MDS/AML (treatment with chemotherapy for previous other diseases is acceptable)

2. Acute promyelocytic leukemia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5517
NTR-old	NTR5644
Other	: 2015-02 LUMC METC

Study results