FLAMSA chemotherapy directly followed by donor stem cell transplantation in elderly patients with acute myeloid leukemia (AML) or high risk myelodysplasia (MDS)

No registrations found.

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

Summary

ID

NL-OMON22287

Source
Nationaal Trial Register

Brief title
FLAMSA TCD NMA AlloSCT

Health condition

AML, acute myeloid leukemia, acute myeloide leukemie, MDS, myelodysplasia, myelodysplasie, allogeneic stem cell transplantation, allogene stamcel transplantatie, donor lymphocyte infusion, DLI, donor lymfocyten infusie.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

1. The number of patients eligible for DLI at 6 months after transplantation;

2. Incidence of non-hematological grade 3-4 toxicity from the start of chemotherapy until 9 months after transplantation;

3. Incidence of serious adverse events from the start of chemotherapy until 9 months after transplantation;

4. Incidence of severe overall grade 3 or 4 acute GvHD and incidence of extensive chronic GvHD in the first 9 months after transplantation;

5. Non-relapse mortality at 3 and 12 months after transplantation.

Secondary outcome

1. One-year progression free survival after transplantation;

2. One-year overall survival after transplantation;

3. Quality of life at 3, 6 and 12 months after transplantation in comparison with quality of life at the start of therapy, as determined with the EORTC QLQ-C30 questionnaire.

Study description

Background summary

This is a phase 1-2 study to determine feasibility and safety of FLAMSA chemotherapy in combination with T cell depleted reduced intensity conditioning allogeneic stem cell transplantation, followed by donor lymphocyte infusion at 3 and 6 months after transplantation, in elderly patients with AML or high risk myelodysplastic syndrome (IPSS >= 1.5).

Study objective

In this study we explore the feasibility of the sequential use of FLAMSA chemotherapy and T cell depleted reduced intensity conditioning allogeneic stem cell transplantation followed by donor lymphocyte infusion at 3 and 6 months after transplantation in patients that are not in complete remission after the first induction chemotherapy. This treatment regimen combines an effective chemotherapy regimen (amsacrine-cytarabine) with a relatively non-toxic

allogeneic transplantation conditioning regimen and a short time between chemotherapy and the time point of DLI administration (3 months). With this TCD FLAMSA-RIC alloSCT regimen we hope to be able to treat and cure more elderly patients with AML and high risk MDS with allogeneic transplantation.

Study design

3, 6 and 12 months after transplantation.

Intervention

Patients will receive FLAMSA chemotherapy over the course of 5 days. After a 3 day rest, the conditioning of the allogeneic stem cell transplantation is started. T cell depletion of the patient consists of alemtuzumab in patients transplanted with a related donor and alemtuzumab in combination with rabbit ATG (Thymoglobulin) in patients with an unrelated donor. No further immunosuppressive drugs are given after transplantation. All patients are to be treated with donor lymphocyte infusions at 3 and 6 months after transplantation.

Contacts

Public
Leids Universitair Centrum, Afdeling Hematologie C2-R, Albinusdreef 2
P.A. Borne, von dem
Leiden 2333 ZA
The Netherlands
071-5262267
Scientific
Leids Universitair Centrum, Afdeling Hematologie C2-R, Albinusdreef 2
P.A. Borne, von dem
Leiden 2333 ZA
The Netherlands
071-5262267

Eligibility criteria

Inclusion criteria

1. Patients with AML or high risk MDS (IPSS >= 1.5);

2. Not in remission after first intensive induction chemotherapy (morphologically > 5% blasts in bone marrow aspirate);

3. 60-75 years, inclusive;

4. HLA-identical sibling or unrelated donor completely matched (10/10 for HLA A, B, C, DR, DQ);

5. WHO-performance status 0-2;

6. Written informed consent.

Exclusion criteria

1. Previous autologous or allogeneic SCT;

2. Acute promyelocytic leukemia;

3. Severe pulmonary dysfunction (CTCAE grade III-IV);

4. Severe cardiac dysfunction (NYHA classification 3-4);

5. Significant hepatic dysfunction (serum bilirubin or transaminases (>= 3 times upper limit of normal);

6. Significant renal dysfunction (creatinine clearance < 30 ml/min after rehydration);

7. Concurrent severe and/or uncontrolled medical condition (e.g. uncontrolled diabetes, infection, hypertension, cancer, etc.);

8. Severe neurological or psychiatric disease;

9. Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule;

10. Patient known to be HIV-positive.

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:	Recruiting
Start date (anticipated):	01-06-2013
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-06-2013
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	NL3854
NTR-old	NTR4014
Other	LUMC METC : 2012-02
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A