Treatment guided by detection of Minimal Residual Disease after allogeneic stem cell transplantation in Acute Myeloid Leukaemia.

No registrations found.

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

Summary

ID

NL-OMON27188

Source
Nationaal Trial Register

Health condition

AML
MRD
Allogeneic stem cell transplantation

Sponsors and support

Primary sponsor: VU University medical center
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Cumulative incidence of (hematological) relapse.

Secondary outcome

1. Relapse free survival;

2. Overall survival;

3. Incidence of acute and chronic GVHD.

Study description

Background summary

Background of the study:

MRD has shown high prognostic value before and after allogeneic transplantation in AML for predicting relapse. It seems likely that using MRD for therapeutic intervention will reduce cumulative incidence of relapse.

Objective of the study:

To decrease the cumulative incidence of (hematological) relapse.

Study design:

Phase II monocenter study.

Study population:

Patients with AML and a leukemia associated phenotype who will undergo an allogeneic stem cell transplantation.

Intervention:

Based on MRD immune suppressive therapy consisting of Mycophenolate Mofetil and Cyclosporine A will be withdrawn early compared to standard practise.

Primary study parameters/outcome of the study:

The cumulative incidence of (hematological) relapse.

Secundary study parameters/outcome of the study:

1. Relapse free survival;

2. Overall survival;

3. Incidence of acute and chronic GVHD.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

no extra punctions will be done, only extra withdrawal of blood and bonemarrow on standard timepoints.

Risk of earlier graft versus host disease after earlier tapering/stop of immunosupressiva, but justified by lowering the cumulative incidence of relapse.

Study objective

to decrease the cumulative incidence of (hematological) relapse.

Study design

Every 4 weeks starting from baseline until day +168.

Intervention

Based on MRD immune suppressive therapy consisting of Mycophenolate Mofetil and Cyclosporine A will be withdrawn early
compared to standard practise. Duration of Ciclosporine A and Mycophenolate Mofetil is dependent on MDR-outcome and the presence of Graft versus Host disease. Mycophenolate Mofetil will be given for a maximum of 84 days and Ciclosporine A for 180 days. There will be no control group.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients with Acute Myeloid Leukemia according to WHO classification 2008;

2. Age 18-75;

3. Indication for allogeneic stem cell transplantation based on risk group profile;

4. Related or unrelated 8/8 HLA matched donor available;

5. Presence of Leukemia Associated Phenotype(s);

6. Written informed consent.

Exclusion criteria

1. Myelodysplastic syndrome with refractory anaemia with excess blasts (RAEB);

2. Acute Promyelocytic Leukemia (AML M3);

3. Absence of LAP(s);

4. Previous allogeneic stem cell transplantation;

5. Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart

failure or
symptomatic ischemic heart disease);

6. Severe pulmonary dysfunction (CTCAE grade III-IV, see appendix D);

7. Severe neurological or psychiatric disease;

8. Significant hepatic dysfunction (serum bilirubin or transaminases => 3 times upper limit of normal)
unless related to treatment;

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

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

11. Patient known to be HIV-positive;

12. Pregnant or breast-feeding female patients;

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

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:	Suspended
Start date (anticipated):	01-04-2013
Enrollment:	31
Type:	Anticipated

Ethics review

Positive opinion
Date: 28-03-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38951
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3769
NTR-old	NTR3927
CCMO	NL43828.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38951

Study results

Summary results
N/A