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

Published: 09-04-2013
Last updated: 19-03-2025

To decrease the cumulative incidence of (hematological) relapse

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON38951

Source
ToetsingOnline

Brief title
VUHEM-MRD-2013

Condition

- Leukaemias

Synonym
acute myeloid leukemia, AML

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: allogeneic stem cell transplantation, AML, MRD

Outcome measures

Primary outcome

The cumulative incidence of (hematological) relapse

Secondary outcome

*Relapse free survival

*Overall survival

*Incidence of acute and chronic GVHD

Study description

Background summary

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.

Study objective

To decrease the cumulative incidence of (hematological) relapse

Study design

Phase II monocenter study

Intervention

Based on MRD immune suppressive therapy consisting of Mycophenolate Mofetil and Cyclosporine A will be withdrawn early compared to standard practise.

Study burden and risks

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

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

*Patients with Acute Myeloid Leukemia according to WHO classification 2008
*Age 18-75
*Indication for allogeneic stem cell transplantation based on risk group profile
*Related or unrelated 8/8 HLA matched donor available
*Presence of Leukemia Associated Phenotype(s) (LAPs)
*Written informed consent

Exclusion criteria

-Myelodysplastic syndrome with refractory anaemia with excess blasts (RAEB)
Acute Promyelocytic Leukemia (AML M3)
-Absence of LAP(s)
-Previous allogeneic stem cell transplantation
-Severe cardiovascular disease (arrhythmias requiring chronic treatment, congestive heart failure or symptomatic ischemic heart disease)
*Severe pulmonary dysfunction (CTCAE grade III-IV, see appendix D)
*Severe neurological or psychiatric disease
*Significant hepatic dysfunction (serum bilirubin or transaminases * 3 times upper limit of normal) unless related to treatment
*Significant renal dysfunction (creatinine clearance < 30 ml/min after rehydration)
*Concurrent severe and/or uncontrolled medical condition (e.g. uncontrolled diabetes, infection, hypertension, cancer, etc.)
*Patient known to be HIV-positive
*Pregnant or breast-feeding female patients
*Any psychological, familial, sociological and geographical condition potentially hampering compliance with the study protocol and follow-up schedule

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2013
Enrollment:	31
Type:	Actual

Medical products/devices used

Product type:	Medicine

Brand name:	CellCept
Generic name:	Mycophenolate mofetil
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Ciclosporin
Generic name:	Ciclosporin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	09-04-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27188
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-000238-37-NL
CCMO	NL43828.029.13

Register	ID
Other	NTR
OMON	NL-OMON27188