A phase I/ II study;Efficacy and safety of alpha / beta T- /CD19B-cell depleted allogeneic haematopoietic stem cells transplantation in high risk or relapsed acute leukaemia / MDS followed by an innate donor lymphocyte infusion (iDLI)

Published: 24-05-2011
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To test feasibility and safety of alpha beta T-/CD19 B-cell depleted allo-SCT in high risk or relapsed acute leukaemia / MDS followed by an innate donor lymphocyte infusion (iDLI)

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

Summary

ID

NL-OMON35919

Source
ToetsingOnline

Brief title
iDLI

Condition

- Leukaemias

Synonym
leukemia bloodcancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Allo-SCT, iDLI, selection

Outcome measures

Primary outcome

Feasibility with respect to engraftment, toxicity in terms of incidence of

graft versus host disease and infectious complications.

Secondary outcome

Immune reconstitution

Progression free survival

Overall survival

Study description

Background summary

Patients suffering from high risk or relapsed leukaemia or high risk MDS can only occasionally be cured with conventional chemotherapy. Allogeneic stem cell transplantation (allo-SCT) has substantially improved the outcome of such patients due to a potent graft versus leukaemia effect after transplantation, but still for the high price of severe and life-threatening GvHD. Also relapses are still observed after allo-SCT.

Study objective

To test feasibility and safety of alpha beta T-/CD19 B-cell depleted allo-SCT in high risk or relapsed acute leukaemia / MDS followed by an innate donor lymphocyte infusion (iDLI)

Study design

Phase I / II
mono center

Intervention

Myeloablative or non-myeloablative conditionering regime followed by alpha / beta and CD 19 B cell depleted stem cell graft.
Short course of ciclosporine.
After discontinuation of ciclosporine and no sign of graft versus host disease a donor lymphocyte inffusion (iDLI) will be given.

Study burden and risks

The protocol compromises a different processing of the donro stem cells source followed by innate DLI (iDLI). All others acts, measurements, follow-up and level of care are similar to off-study patients undergoing allo-SCT. The burden of the therapy is associated with the allo-SCT itself which is a necessary therapeutic intervention in all subjects. Possible increased risk of acute and chronic exist due to the earlier application of immune cells. There is a possible increased risk of engraftment failure due to T cell depletion. However, we expect a lower mortality, secure engraftment, and less relapse and infection due to NK- and gamma/ delta cell activilty as well as lower risk of acute and chronic GVHD.

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

Age 18-65 years
Meeting the criteria for an allo-SCT and high risk leukemic disease
WHO PS status <= 2
Written informed consent

Exclusion criteria

Relapse of allo-SCT within 6 months after allo-SCT
Relapse acute promyelocyten leukemia
Bilirubin and/or transaminases > 2.5 x normal value
Creatinine clearance < 40 ml/min
Cardiac dysfunction as defined by:
Unstable angina
Unstable cardiac arrhythmias
Active, uncontrolled infection
HIV positivity

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cels allogenic

Ethics review

Approved WMO Date:	24-05-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	11-07-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Not approved Date:	19-03-2012
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2010-021221-12-NL
CCMO	NL36365.000.11
Other	NTR