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: 22-12-2010
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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)

Ethical review	Not approved
Status	Will not start
Health condition type	Leukaemias
Study type	Interventional

Summary

ID

NL-OMON34123

Source
ToetsingOnline

Brief title
Allo-SCT and innate donor lymphocyte infusion

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

Main study parameters/endpoints: Feasibility with respect to engraftment,

toxicity in terms of incidence of GvHD 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

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

Study design: Phase I/II study

Intervention

Intervention: Myeloablative or non-myeloablative conditioning regime,alpha / beta T-/CD19 B-cell depleted stem cell graft, short immunosuppression with ciclosporine, immunomodulation with zoledronic acid and innate donor lymphocyte infusion (iDLI).

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The protocol comprises a different processing of the donor stem cells source followed by innate DLI (iDLI). All other 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 risks of acute and cGvHD exist due to the earlier application of immune cells. There is a possible increased risk engraftment failure due to T cell depletion. However, we expect a lower mortality, secure engraftment, and less relapse and infection due to NK- and **T-cell activity as well as a lower risk of aGvHD and cGvHD

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 a allo-SCT and high risk leukemic disease
WHO performance 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
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:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cels allogenic
Product type:	Medicine
Brand name:	zometa
Generic name:	zoledronic acid
Registration:	Yes - NL outside intended use

Ethics review

Not approved

Date:	22-12-2010
Application type:	First submission
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	NL33076.000.10