A phase II study to assess engraftment and engraftment kinetics after double cord blood transplantation with a reduced-intensity conditioning regimen in patients eligible for allogeneic stem cell transplantation lacking a matched unrelated donor.

Published: 15-05-2008
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Evaluation of engraftment and disease-free survival following double cord blood transplantation after a reduced intensity conditioning regimen in adult patients. In addition to description of clinical parameters biological studies will be performed…

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

Summary

ID

NL-OMON35273

Source
ToetsingOnline

Brief title
HO106 Double UCBT

Condition

- Leukaemias
- Leukaemias

Synonym

Acute Leukemia; Cancer of bone marrow

Research involving
Human

Sponsors and support

Primary sponsor: HOVON
Source(s) of monetary or material Support: KWF Kankerbestrijding;Stichting HOVON

Intervention

Keyword: Allogeneic stem cell transplantation, Double cord blood transplantation, Engraftment

Outcome measures

Primary outcome

Primary endpoint is the cumulative incidence of graft failure.

Secondary outcome

Secundary end points: time to engraftment of different cell lines, incidence of

graft vs host disease, incidence of infection, TRM, disease-free survival and

overall survival.

Study description

Background summary

Many adults with high risk hematological disease can not proceed to allogeneic stem cell transplantation because they lack a matched unrelated stem cell donor. Cord blood transplantation has shown to be an important alternative stem cell source in children. The major problem after a single cord blood transplantation in adults appears to be primary graft failure and a delayed hematopoietic recovery caused by the small number of hematopoietic stem cells in cord blood grafts. Double cord blood transplantation has shown to be a safe and promising approach in adult to overcome this problem. Sustained hematopoiesis is usually derived from a single donor after double umbilical cord blood transplantation.So far, the distinct contributing factors which lead to the predominance of the prevailing cord blood graft are not known.

Study objective

Evaluation of engraftment and disease-free survival following double cord blood transplantation after a reduced intensity conditioning regimen in adult patients. In addition to description of clinical parameters biological studies will be performed in order to evaluate whether parameters can be identified that predict which graft ultimately prevails.

Study design

Prospective phase II study. Patients eligible for allogeneic stem cell transplantation lacking a matched unrelated donor are transplanted with a double cord blood graft. Transplantation will be preceded by a reduced-intensity conditioning regimen. After transplantation blood samples and bone marrow samples will be collected at certain time points.

Intervention

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Study burden and risks

Nature and extend of the burden and risks associated with participation
Burden and risk are comparable to burden and risk of a standard cord blood transplant procedure. Collection of blood samples may be a small extra burden if extra venous puncture is necessary. Collection of bone marrow samples can give a small inconvenience because a larger volume of bone marrow has to be collected compared to standard bone marrow examination.

Contacts

Public
HOVON

Postbus 7057
1007 MB Amsterdam
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Scientific
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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 65 years old or younger. High risk disease as specified in protocol. Lacking a sufficiently matched volunteer unrelated donor or lacking such a donor within the required timeperiod of no more than 2 months in case of urgently needed alloSCT. Availability of 2 sufficiently matched UCB grafts with a total nulear cell count > 4 x 10 7/kg.

Exclusion criteria

Bilirubin and/of transaminases > 2.5 x normal value. Creatininge clearance < 40 ml/min. Active, uncontrolled infection. Cardia dysfunction. Pulmonary dysfunction test with VC, FEV1 and/of DCO < 50%. History of high/dose total body irradiation. 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):	26-11-2008
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cels allogenic

Ethics review

Approved WMO Date:	15-05-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	04-06-2008
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-03-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	17-09-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-11-2009
Application type:	Amendment

Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	19-11-2009
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	02-03-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-06-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	01-07-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	14-09-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	30-11-2010
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	16-05-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO	

Date:	30-06-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Not approved

Date:	21-07-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO

Date:	19-11-2011
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Not approved

Date:	20-12-2011
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	EUCTR2008-000053-35-NL
CCMO	NL18416.000.08