Prophylactic infusion of CD4 positive donor lymphocytes early after T-cell depleted allogeneic stem cell transplantation in patients with an unrelated donor

Published: 08-06-2012
Last updated: 26-04-2024

In this phase II study, the toxicity and treatment effects of early donor derived CD4+ lymphocyte infusion, three months after allo-SCT, will be evaluated

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

Summary

ID

NL-OMON37250

Source
ToetsingOnline

Brief title
CD4+ donor lymphocytes

Condition

- Other condition
- Leukaemias

Synonym
hematological malignant diseases

Health condition

Andere hematologische maligniteiten (multipel myeloom, lymfoom)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Donor lymphocyte infusion, Immune reconstitution, Stem cell transplantation

Outcome measures

Primary outcome

• The number of circulating naïve CD4+ lymphocytes 4.5 months after allo-SCT.

Secondary outcome

• Chimerism of circulating lymphocytes.

• Transplantation related complications between 3 and 12 months after the transplantation (CMV disease or CMV reactivation needing systemic treatment, EBV reactivation needing systemic treatment, VZV infection, other infections for which hospitalization, GVHD needing systemic treatment, auto-immune disorders needing systemic treatment).

Study description

Background summary

Allo-SCT provides potentially curative therapy for patients with a variety of hematologic malignancies. However, acute GVHD and its treatment are major causes of transplant-related morbidity and mortality. The most efficient method for prevention of GVHD consists of T-cell depletion of the graft. Allo-SCT regimens using the CD52 antibody alemtuzumab for T-cell depletion demonstrate efficient engraftment and reduced acute GVHD. However, these protocols substantially impair post-transplant antiviral and antitumor immunity. Patients show a poor immune reconstitution, particularly with slow recovery of the CD4+

T-cell subset.

Study objective

In this phase II study, the toxicity and treatment effects of early donor derived CD4+ lymphocyte infusion, three months after allo-SCT, will be evaluated

Study design

Randomized open label single centre intervention study

Intervention

Infusion of CD4+ lymphocytes at three months after the transplantation

Study burden and risks

Participating patients will visit the outpatient clinic once every two weeks for physical examination and blood sampling, which is at this moment the standard care for patients during the first six months after allo-SCT at our institution. The total amount of blood which will be taken for study purposes will be maximally 250 cc in a three months period. One extra bone marrow examination will be performed (six weeks after CD4+ infusion). The risk of CD4+ donor lymphocyte infusion is acute GVHD, as is seen in patients receiving total donor lymphocyte infusion after allo-SCT. Potential benefit is a faster immune reconstitution. If chimerism converts to donor, further unmodified DLIs could be omitted.

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 years
• Patients with AML, myelodysplasia , ALL, CML in accelerated phase or blastic transformation, CLL, MM or (non) Hodgkin lymphoma, who underwent an allo-SCT with an unrelated 10/10 matched donor (matched for HLA-A, B, C, DR and DQ)
• Life expectation of > 3 months
• WHO performance status of 0, 1 or 2
• Written informed consent according to the rules and regulations of the Leiden University Medical Center.

Exclusion criteria

• Use of systemic immunosuppressive treatment (due to GVHD)
• Acute GVHD of the skin > grade 2 or progressive acute GVHD
• Progressive disease needing cytoreductive treatment
• Any concomitant disease preventing the safe administration of donor lymphocytes
• Severe psychological disturbances
• Severely limited life expectation due to diseases other than the malignancy
• Very high risk disease preceding allo-SCT for which already unselected DLI is planned to be given 3 months after allo-SCT.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-10-2012
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cels allogenic

Ethics review

Approved WMO Date:	08-06-2012
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Approved WMO Date:	21-08-2012
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	EUCTR2012-002418-38-NL
CCMO	NL40884.000.12