TREATMENT WITH CYTOMEGALOVIRUS (CMV) PP65-SPECIFIC LYPHOCYTES IN PATIENTS WITH CMV REACTIVATION OR CMV DISEASE AFTER ALLOGENEIC STEM CELL TRANSPLANTATION.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24017

Source
NTR

Brief title
CMV pp65 specific T cells

Health condition

CMV reactivation
CMV disease
CMV reactivatie
CMV ziekte
virusreactivatie

Sponsors and support

Primary sponsor: Leiden University Mecical Center
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The number of events of acute GvHD, death and all other adverse events.

Secondary outcome

1. The number of CMV-specific T cells at different time points after infusion of CMV pp65-specific T cells;

2. The number of complete responses or partial responses of CMV reactivation or CMV disease after infusion of CMV pp65-specific T cells.

Study description

Background summary

This is an open-label non-randomized phase I/II feasibility study to treat patients with persistent CMV reactivation or CMV disease after alloSCT with administration of CMV pp65-specific T cells generated by use of a CMV pp65 protein-spanning peptide pool.

Patients after alloSCT with a CMV seropositive donor will be monitored weekly for CMV reactivation using PCR for the detection of CMV DNA. In case of CMV reactivation (defined as CMV DNA load >1000 cp/ml) patients will be treated with antiviral therapy according to standard protocols.

For patients with CMV reactivation who fail antiviral therapy (defined as CMV reactivation treatment failure: persistent CMV DNA load of more than 1000 cp/ml or CMV disease after 2 weeks of adequate treatment with antiviral therapy or relapse of CMV DNA load of more than 1000
cp/ml within 4 weeks after adequate treatment with antiviral therapy or contraindication for treatment with antiviral therapy at the discretion of the physician) or develop CMV disease (organ dysfunction (pneumonitis, enteritis, retinitis, encephalitis, hepatitis, and bone marrow suppression) due to CMV infection), CMV pp65-specific CD4+ and CD8+ T cells will be generated from donor PBMC by overnight in vitro stimulation with CMV pp65 peptide pools. CMV-specific CD4+ and CD8+ T cells will be isolated based on their IFNg production and administered to the patient directly after quality control. If alloSCT was performed using CD34 positive cell selection and the CD34 negative subfraction has been cryopreserved at a GMP facility, this fraction can also be used for selection of CMV-specific T cells. Antiviral therapy will be continued after infusion of CMV pp65-specific T cells according to standard

antiviral treatment protocols at the discretion of the physician.
In case of ongoing CMV reactivation or CMV disease the infusion of CMV pp65-specific T cells may be repeated 2 times with at least 4 weeks interval. The patient will be monitored for adverse events and for effect on CMV DNA load. Follow-up of patients will be performed until 6 months after infusion of CMV pp65-specific T cells or until subsequent DLI, whichever comes first.

Study objective

N/A

Study design

1. Weekly, first 3 months after infusion;

2. Monthly, 3-6 moths after infusion.

Intervention

Infusion of CMV pp65-specific T-cells.

Contacts

Public
P.O. Box 9600
P. Balen, van
Leiden 2300 RC
The Netherlands
+31 (0)71 5262267
Scientific
P.O. Box 9600
P. Balen, van
Leiden 2300 RC
The Netherlands
+31 (0)71 5262267

Eligibility criteria

Inclusion criteria

1. Age 0-75 years;

2. Recipient of alloSCT for standard indication according to national- and European Group for blood and Marrow Transplantation-guidelines (see appendix D);

3. Possibility to obtain PBMC by leukapheresis from the CMV seropositive donor or availability of peripheral blood stem cell graft (PBSCT) or of a CD34-negative subfraction of a CD34-positively selected PBSCT product of the donor prepared and cryopreserved at a GMP-facility or stem cell center;

4. CMV reactivation treatment failure (persistent CMV DNA load of more than 1000 cp/ml or CMV disease after 2 weeks of adequate treatment with antiviral therapy or relapse of CMV DNA load of more than 1000 cp/ml within 4 weeks after adequate treatment with antiviral therapy or contraindication for treatment with antiviral therapy at the discretion of the physician) or CMV disease (organ dysfunction (pneumonitis, enteritis, retinitis, encephalitis, hepatitis, and bone marrow suppression) due to CMV infection);

5. Written informed consent by the patient and/or parent(s) or legal guardian(s).

Exclusion criteria

1. Life expectation < 3 months;

2. End stage irreversible multi-system organ failure;

3. Pregnant or lactating women;

4. Severe psychological disturbances;

5. Patient HIV positive;

6. Donor HIV positive.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2011
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-12-2011
Application type:	First submission

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
NTR-new	NL3046
NTR-old	NTR3194
Other	METC LUMC : 2010-03
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A