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

Gepubliceerd: 13-12-2011 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24017

Bron
NTR

Verkorte titel
CMV pp65 specific T cells

Aandoening

CMV reactivation
CMV disease
CMV reactivatie
CMV ziekte
virusreactivatie

Ondersteuning

Primaire sponsor: Leiden University Mecical Center
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

1. Weekly, first 3 months after infusion;

2. Monthly, 3-6 moths after infusion.

Onderzoeksproduct en/of interventie

Infusion of CMV pp65-specific T-cells.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-11-2011
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3046
NTR-old	NTR3194
Ander register	METC LUMC : 2010-03
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A