Transfer of multiantigen-specific T cells after allogeneic stem cell transplantation

Gepubliceerd: 22-09-2014 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON25777

Bron
NTR

Verkorte titel
T control

Aandoening

Patients with a haematological malignancy who are planned to undergo an allogeneic stem cell transplantation

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC)
Overige ondersteuning: European Union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the efficacy of the transfer of multiantigen specific T cells by measuring the appearance or expansion (if antigenic specific donor derived cells are already present in the circulation of the patient at time of infusion) of antigen specific donor derived T cells during eight weeks after the infusion of donor derived multi antigen specific T cells.

Toelichting onderzoek

Achtergrond van het onderzoek

This is a non-randomized phase I/II study to analyze the feasibility and safety of administration of multiantigen-specific T cells generated using sets of multiantigen-specific streptamers based on the patients and donors HLA type for the prevention of infectious complications and early relapse or disease progression after T cell depleted allo-SCT. Only patients with HLA type A*0201 will be included since at present only streptamers specific for the TAA and MiHA in the context of HLA-A2 are available, necessary for evaluation of the immunological endpoints of the study. As part of a European collaborative project T-Control, the same study will be performed at 2 centers in Europe in two different patient cohorts after T cell depleted allo-SCT to allow appropriate evaluation of the potential broad applicability of this therapy. We aim to evaluate the effects of this intervention in 17 patients treated at the Leiden University Medical Center (LUMC) following allo-SCT with in-vitro T cell depletion using alemtuzumab. Seventeen patients will be treated at the Wurzburg University Medical Center following allo-SCT using CD34 selection for in-vitro T cell depletion.

Onderzoeksopzet

Every week during first 8 weeks. Thereafter every two weeks until 20 weeks after allo-SCT.

Onderzoeksproduct en/of interventie

derived multi-antigen specific T cells

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18-75 years

- Planned T cell depleted allo-SCT for one of these diagnoses:

o Acute Lymphoblastic Leukemia in CR after prephase and first induction and consolidation therapy and WBC < 30 x 109/l in B-ALL or < 100 x 109/l in T-ALL at initial diagnosis. ALL with t(9;22), t(4;11), complex karyotype or 11q23 abnormalities will be excluded.

o Acute Myeloid Leukemia in CR excluding AML with:

* Monosomal Karyotype

* Abn3q26

* EVI1 overexpression

o Multiple myeloma at least in stable PR (no treatment foreseen in first 6 months after allo-SCT)

o Non high grade B-NHL (B-CLL, Mantle cell lymphoma, Follicular Lymphoma, MALT, LPL) at least in stable PR (no treatment foreseen in first 6 months after allo-SCT)

o Myeloprolypherative disorder at least in stable PR (no treatment foreseen in first 6 months after allo-SCT), excluding CML blastic phase

o Myelodysplastic syndrome at least in stable PR (no treatment foreseen in first 6 months after allo-SCT)

- HLA type A*0201.

- Written informed consent of the patient

- Availability of a stem cell donor who meets the following inclusion criteria:

o HLA type A*0201

o CMV and/ or EBV seropositivity

o Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Disease specific treatment foreseen in the first 6 months after SCT

- Life expectation < 6 months.

- End stage irreversible multi-system organ failure (need for mechanical ventilation, hypotension for which admission to ICU, hepatic encephalopathy, coma).

- Pregnant or lactating women or women with child bearing potential who are unwilling or not capable to use effective means of birth control.

- Severe psychological disturbances.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	17
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-09-2014
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	NL4658
NTR-old	NTR4801
Ander register	: LUMC 2014-01

Resultaten