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

No registrations found.

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

Summary

ID

NL-OMON25777

Source
NTR

Brief title
T control

Health condition

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

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: European Union

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

To assess the feasibility and safety (toxicity) of the administration of donor derived multi antigen specific T cells early after T cell depleted allo-SCT.

Study description

Background summary

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.

Study design

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

Intervention

derived multi-antigen specific T cells

Contacts

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Eligibility criteria

Inclusion criteria

- 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

Exclusion criteria

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	17
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-09-2014
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	NL4658
NTR-old	NTR4801
Other	: LUMC 2014-01

Study results