ADMINISTRATION OF HA-1 TCR TRANSDUCED VIRUS-SPECIFIC T-CELLS AFTER ALLOGENEIC STEM CELL TRANSPLANTATION IN PATIENTS WITH HIGH-RISK LEUKEMIA.

No registrations found.

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

Summary

ID

NL-OMON26148

Source
Nationaal Trial Register

Brief title
HA-1 TCR transduced virus-specific T-cells

Health condition

high risk leukemia

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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

2. The feasibility of generation of HA-1 TCR transduced virus-specific donor T-cells.

Secondary outcome

1. The number of HA-1 TCR transduced virus-specific donor T-cells in blood or bone marrow at different time points;

2. The number of patients eligible for standard DLI at 6 months.

Study description

Background summary

This is an open-label non-randomized phase I/II feasibility study to treat patients with high-risk leukemia with HA-1 TCR
transduced virus-specific donor-derived T-cells 8 and 14 weeks after allo-SCT.
The HA-1 TCR transduced virus-specific T-cells will be generated from donor leukocytes obtained from a leukapheresis product of the stem cell donor. Minimally one and maximally two CMV- and/or EBV-specific T cell populations will be isolated from PBMC using Streptamers. After 2-3 days of culture, virus-specific T-cells are transduced with a retroviral vector encoding the HA-1-TCR. After 8-12 days of additional culturing, the transduced virus-specific T-cells will be analyzed for virus-specific T-cell purity and HA-1-TCR cell surface expression using virus- and HA-1-specific tetramers. For release of the HA-1-TCR transduced virus-specific T-cells, ¡Ý 95% of the cell product must be T-cells, ¡Ý 60% of T-cells must be antigen-specific as measured with tetramers specific for the endogenous virus-TCR and introduced HA-1-TCR, and ¡Ý5% of lymphocytes must be HA-1-tetramer positive. The maximal amount of virus- or HA-1-tetramer negative T-cells with unknown specificity administered in the T-cell product is <0.3 x 106 cells/kg body weight in patients transplanted with HLA-matched related donors and <0.15 x 106 cells/kg body weight in patients transplanted with unrelated donors or HLA-A2 mismatched donors.

Study objective

N/A

Study design

1. Weekly, first 8 weeks after infusion(s);

2. Three weekly, next 2-3 months.

Intervention

Infusion of manipulated donor lymphocytes consisting HA-1 T-cell receptor (TCR) transduced virus-specific donor T-cells 8 weeks after allogeneic stem cell transplantation (allo-SCT). This infusion may be repeated 6 weeks later.

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 18-75 years;

2. WHO performance score 0-2;

3. High-risk leukemia;

4. Complete remission (CR) or stable partial remission (PR);

5. HLA-A*0201 positive;

6. HA-1h positive;

7. Availability of a suitable donor;

8. Written informed consent.

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. HIV-positivity.

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:	Pending
Start date (anticipated):	01-06-2012
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-05-2012
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	NL3307
NTR-old	NTR3454
Other	METC LUMC : 2010-03
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A