Generation of precursor T cells dor the development of adoptive T cell therapy for patients after stem cell transplantation.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON36844

Source
ToetsingOnline

Brief title
Generation of precursor T cells form donor stem cells.

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Acute leukemia, blood cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W,KWF

Intervention

Keyword: CD34, precursor T cells, stem cells

Outcome measures

Primary outcome

Because there are no groups or populations in this study and only biological

material (stem cells) is needed, there are no primary study parameters.

Secondary outcome

Because there are no groups or populations in this study and only biological

material (stem cells) is needed, there are no secundary study parameters.

Study description

Background summary

The central aim of this project is to improve immune reconstitution and decrease the morbidity of patients that have received a hematopoietic stem cell transplant (HSCT) in line with their anti-cancer treatment. Even thought HSCT cures patients from cancer, there is a delay in generation of pro-thymocytes that are required to initiate T cell production by the thymus. The enduring T cell lymphopenia causes that too many patients die because of oppurtunistic infections.

Study objective

The ultimate goal is to develop an early T cell reconstition therapy to combine with HSCT to treat and cure patients with hematological cancers. In this stage, thus for this project, we need to investigate if we can make in vitro T cell from CD34+ hematopoietic stem cells in a GMP compliant system. We can isolate these stem cells from leucaferesis products obtained from healthy volunteers treated with G-CSF.

Study design

This study concerns only in vitro experiments which will be performed with stem

cells obtained from leucaferis product from healthy volunteers.
CD34+ stem cells will be isolated from the leucaferesis product. In vitro experiments will be performed with the stem cells to investigate whether they have T cell potential. The cells will be discarded after analysis.

Study burden and risks

The extent of the burden is low. The study will only be of short duration. Before the start of the study, the volunteer will be medically examined. This will take approximately 30 minutes. During 5 days the donor will inject him/herself subcutaneous with G-CSF, this can be performed at home. The donor will be instructed about this procedure. Hereafter the leucaferese will follow, this will take about 4 hours. Needles will be placed in both arms, therefore the donor is not able to move a lot during the 4 hours. The procedure is already carried out in the hospital as a standard for stem cell transplantation. Therefore, the staff will be familiar with the procedure. This will comfort the donor and if side effects appear the doctor can act fast.

G-CSF is normally well taken. It can cause temporary discomfort:

- 80% of the donors have bone pain and/or headache. 25% suffers from muscle ache.
- 0.1-1% suffers from spleen abnormalities, among which an enlarged spleen and very rare rupture.
- In rare cases donors can experience cardiac complaints. This is only observed in donors with cardiac risk factors.

The leucaferesis itself is of low burden. Side effects can be a tingling feeling near the mouth and in the fingertips. This can be ended by giving the donor calcium. For example by giving the donor milk or yoghurt.
Some donors endure fatigue after the leucaferesis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy volunteers, age >=18<= 60 year

Exclusion criteria

Every chronical disease were G-CSF administration is a risk factor. More specific: Cardiovascular diseases, including hypertension, and malignancies.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-04-2013
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	08-10-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL40886.068.12