Are intrinsic defects of the stem cell compartment responsible for the peripheral pancytopenia post-transplantation.

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- To determine the numbers of dividing cells focused whether hyperproliferation or hypoplasia can be determined.- To determine whether the progenotor or stem cell is different affected.- Can intrinsic defects of the CD34+ cells be demonstrated that...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Haematopoietic neoplasms (excl leukaemias and lymphomas)
Study type	Observational invasive

Summary

ID

NL-OMON29955

Source
ToetsingOnline

Brief title
ASCT; pancytopenia

Condition

- Haematopoietic neoplasms (excl leukaemias and lymphomas)

Synonym
Autologous stem cell transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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

Intervention

Keyword: ASCT, stem cell defect

Outcome measures

Primary outcome

- In-vitro culture assay of CD34+ cells.

- Phenotypic characterization of the CD34+ cell population.

- Micro-array analysis of CD34+ cells.

- FLT-PET

Secondary outcome

Not applicable

Study description

Background summary

A high number of patients have a persistent pancytopenia during a number of months after the transplantation. The cause of this finding has not been elucidated but might be caused by an inadequate homing of the stem cells during the transplantation procedure, related to the chemotherapy applied before the transplantation on due to a ongoing stress-response which affects strongly the properties of the stemcell compartment.

Study objective

- To determine the numbers of dividing cells focused whether hyperproliferation or hypoplasia can be determined.
- To determine whether the progenotor or stem cell is different affected.
- Can intrinsic defects of the CD34+ cells be demonstrated that correlate with the observed abnormalities.

Study design

On basis of these findings in-vitro parameters of the bone marrow compartment

will be analyzed. In addition the total bone marrow compartment will be visualized by FLT-PET.

Study burden and risks

- Local pain due to bone marrow aspirate.
- Time related to FLT-PET and intra venous injection of the tracer.

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

ASCT

Exclusion criteria

Persistent disease activity in the bone marrow.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2007
Enrollment:	0
Type:	Actual

Ethics review

Approved WMO

Date:	14-09-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL13858.042.06