Bone marrow evaluation in patients with suspected aplastic anemia

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In our laboratory we are able to characterize and culture MSCs. In order to study more extensively the possible alterations in MSC biology in AA we will investigate bone marrow cells of patients with newly diagnosed AA and at the time of response…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Anaemias nonhaemolytic and marrow depression
Study type	Observational non invasive

Summary

ID

NL-OMON42036

Source
ToetsingOnline

Brief title
Bone marrow evaluation in patients with suspected aplastic anemia

Condition

- Anaemias nonhaemolytic and marrow depression

Synonym
aplastic anemia

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: aplastic anemia, bone marrow

Outcome measures

Primary outcome

The functional characterization of MSC*s in AA by gene expression profiling and

in vitro behavior

Secondary outcome

Exploratory analysis correlation between response on immunosuppressive therapy

and MSC characteristics at presentation

Study description

Background summary

Acquired aplastic anemia (AA) is a hematopoietic stem cell (HSC) disease associated with bone marrow (BM) failure reflected by markedly reduced cellularity and deficient blood cell production. The pathophysiology of the disease is still not completely resolved; however aberrant activation of the immune system towards the HSC of the patient seems to play a central role. It is well known that after an inciting event, such as drug exposure or viral infection, the hematopoietic compartment can be destroyed by the immune system. Small numbers of surviving stem cells support adequate hematopoiesis for some time, but eventually the cell counts become very low and symptoms appear. The attaque on the bone marrow compartment might not only linked to hematopoietic stem cells but might also be directed to the surrounding microenvironment including mesenchymal stem cells (MSCs). MSCs play an important role in providing the specialized bone marrow microenvironment for hematopoietic stem cell survival and differentiation alterations and defects of these cells in AA have been described. Furthermore, co-transplantation of haploidentical mesenchymal stem cells to enhance engraftment of hematopoietic stem cells and to reduce the risk of graft failure in patients with failure has also been published supporting the role of MSC in AA.

Study objective

In our laboratory we are able to characterize and culture MSCs. In order to

study more extensively the possible alterations in MSC biology in AA we will investigate bone marrow cells of patients with newly diagnosed AA and at the time of response evaluation after immunosuppressive therapy.

Study design

In patients diagnosed with aplastic anemia additional bone marrow cells (20 ml) will be collected during the standard diagnostic and first evaluation bone marrow test

Study burden and risks

At the standard procedure of diagnostic and first evaluation bone marrow punction 20 ml extra marrow is drawn. This increases the procedure with 2 minutes. There are no additional punctions done.

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

Patients with suspected a plastic anemia patients undergoing a diagnostic and first evaluation bone marrow-biopsy

Exclusion criteria

Age < 18 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2015
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	NL50636.042.14