Quantify the mesenchymal population and the osteogenic differentiation of bone marrow cells

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To quantify the MSC population of concentrated bone marrow aspirate and examine their differential potentials and the variation among patients and examine similarities and differences with the current literature.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Joint disorders
Study type	Observational invasive

Summary

ID

NL-OMON41207

Source
ToetsingOnline

Brief title
bone marrow compensition

Condition

- Joint disorders

Synonym
orthopedic differentiation of stem cells

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Marti-Keuning Eckhart Stichting

Intervention

Keyword: bone marrow, mensenchymal, osteoprogenitor, stem cell

Outcome measures

Primary outcome

Avarage number of stem cells available in a bone marrow aspirate and the

different cell typesin %.

Secondary outcome

Number of stem cells with bone or vascular generating potentials (through:

CD34, CD45, CD90, CD105, CD146, CD271 markers)

Colony forming potentials of stem cells (through CFU-F analysis)

Genexpressie of the osteoprogenitors (through PCR analyse)

Other baseline parameters will be noted to detect potential confounders: sex,

smoking, current diets, age and body weight.

Study parameters will be compared between patients and also to the existing

literature.

Study description

Background summary

Bone marrow cells (BMC) are rich of mesenchymal stem cells (MSC). These MSCs do have clinical potential in orthopaedics because they give rise to the cells that form mesenchymal tissues like bone and cartilage and they can be easily obtained and concentrated from bone marrow. Only little evidence is available of its content and the constancy of it among different patients, though research suggest a correlation between amount of progenitor cells and healing potentials of bone marrow aspirate at the affected area.

Study objective

To quantify the MSC population of concentrated bone marrow aspirate and examine their differential potentials and the variation among patients and examine similarities and differences with the current literature.

Study design

Non-invasive observational pilot study.

Bone marrow aspirate will be collected of 10 patients who suffer from a bonedefect wherefor they need a autologous cancellous bone graft of the anterior iliac crest (under general anesthesia).
If these patients meet all established criteria, they will be informed about the research and sign the informed consent form if they want to participate.
During the surgery when bone graft is obtained, we use this route to aspirate 30cc bone marrow. The surgical procedure will continue directly after this. The local researcher will perform the other procedures and then transport the aspirate to the laboratory where the analysis will be performed. There will be no follow-up of the patients.
Composition will be examined and results will be noted and compared to the existing literature and mutually between patients.

Study burden and risks

This non-therapeutic research is of minor/negligible burden for the patient. Because the osteogenic quality of bone marrow aspirates and its consistency between patients is barely studied before, this can give us a great amount of new and usefull information for future stem cell therapies in orthopedic surgery, like non-union and fracture healing or prevention of osteoarthritis.
The risk to the patient can be considered minimal and the benefits of knowing more about the basic qualities of bone marrow aspirates in orthopaedics would greatly benefit its potentials and value in clinical orthopaedic population.

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
- in need of an autologous bone graft harvested of the (anterior or posterior) iliac crest for orthopaedic reason;
- understand study proposal and sign informed consent;
- > 18 years old

Exclusion criteria

Subjects:
- participating in other studies
- suffering from an autoimmune disease
- suffering from an infection
- suffering from a malignancy
- receiving or received chemotherapy / other bone marrow suppression medicine < 1 year ago
- suffering or suffered from a hematopoietic disease < 1 year ago
- an other known malignancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Approved WMO

Date:	07-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL47846.018.14