Biomarkers of cartilage and bone damage after joint bleeds in haemophiliacs

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Evaluation of acute joint damage immediately after a joint bleed in patients with haemophilia, by use of a panel of state-of-the-art biomarkers of cartilage and bone turnover measured in blood and urine. The question that will be addressed is...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON39118

Source
ToetsingOnline

Brief title
Biomarkers after joint bleeds in haemophiliacs

Condition

- Haematological disorders NEC
- Joint disorders

Synonym
clotting factor VIII/IX deficiency

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biomarkers, Bone, Cartilage, Haemophilia

Outcome measures

Primary outcome

Biomarkers of cartilage and bone turnover.

Secondary outcome

not applicable

Study description

Background summary

Haemophilia is an X-chromosome linked, recessive bleeding disorder due to a deficiency or functional defect of coagulation factor VIII or IX. Due to recurrent joint bleeds (haemarthroses) specific changes occur in synovium and cartilage in joints of patients suffering from haemophilia. In vitro and animal in vivo experiments suggest that a single joint bleed results in rather acute adverse changes in cartilage. These acute adverse changes of a single bleed on cartilage, relatively easily detectable in vitro and animal models, are difficult to detect in humans. Therefore, there is a need for more sensitive measures that describe degenerative joint changes in the process of blood-induced joint damage. This would improve early diagnosis, evaluation of damage during the course of disease, and could have its impact on treatment of haemophilia.
Biomarkers for cartilage and bone damage could be such a tool. Biomarkers are molecules of connective tissue matrices, which are released into biological fluid during the process of tissue turnover. Several (immuno)-assays have been developed to detect such components, reflecting degradation and/or repair activity of the tissue, in easily accessible body fluids such as serum and urine. Recently several biomarkers of cartilage and bone related to the joint diseases osteoarthritis and rheumatoid arthritis have been studied. These biomarkers may also be used for detection of joint damage after a joint bleed in haemophiliacs.

Study objective

Evaluation of acute joint damage immediately after a joint bleed in patients with haemophilia, by use of a panel of state-of-the-art biomarkers of cartilage

and bone turnover measured in blood and urine. The question that will be addressed is whether joint damage as a result of an acute joint bleed in haemophiliacs can be detected by use of a panel of state-of-the-art biomarkers of cartilage and bone turnover.

Study design

Patients with haemophilia, being eighteen years or older, that visit the Van Creveld Clinic for treatment of a joint bleed will be asked to participate in this study. Initially a total of 10 patients will be included. Blood and urine samples will be collected at four time-points after a joint bleed: within <48 hours, between 3 and 5 days, between 12 and 14 days and 3 months after the joint bleed. Most haemophilia patients are used to vena puncture themselves to administer clotting factor routinely. They will be demonstrated once how to draw blood instead of administer clotting factor. Patients will take 10 ml blood samples by venous puncture and will keep it at room temperature. Urine (about 30 ml in a 50 ml vessel) will be collected, preferably the second morning urine, and kept at 4*C (refrigerator). Blood and urine samples taken will be collected by the researcher. Patients who can not or are not willing to draw blood themselves, can come to the Van Creveld Clinic and an experienced nurse will perform the venous puncture.
Serum and urine samples will be analysed for state-of-the-art biomarkers.
This study will last 3 months for each patient. Blood and urine will be collected at four specific time-points (within <48 hours, between 3 and 5 days, between 12 and 14 days and 3 months after the joint bleed), either in the Van Creveld Clinic or at home.

Study burden and risks

There are no considerable risks nor benefits for the patients.

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

Haemophilia, joint bleed

Exclusion criteria

HIV positivity, overweight, antibodies against clotting factor

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-01-2009

Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	18-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-03-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL17932.041.07