Medial arterial calcification in patients with hemophilia

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The primary objective will be the prevalence of medial arterial calcification, defined as an ABI * 1.3 and a TBI > 0.7, among hemophiliacs compared with non- hemophiliacs matched by sex and age.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON44851

Source
ToetsingOnline

Brief title
MIRACLE study

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Medial arterial calcification - calcification in the middle layer of the vascular wall

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Unrestrictred research grant van Bayer B.V.

Intervention

Keyword: Ankle Brachial Index (ABI), Hemophilia, Medial arterial calcification (MAC)

Outcome measures

Primary outcome

The main study parameter is the ABI in patients with haemophilia as compared to

control subjects.

Secondary outcome

Not applicable

Study description

Background summary

Cross- sectional studies recently showed that patients with hemophilia develop atherosclerosis to the same extent as in the general population, as measured by intima media thickness of the carotid arteries and coronary calcium score. Intima calcification is considered to be a characteristic lesion in the atherosclerotic process. However, calcifications develop at two sites of the arterial wall: the intima and the media as well.

Medial arterial calcification (MAC), contrary to intima calcification, is a non-occlusive condition leading to arterial stiffening. MAC occurs in muscle-type conduit arteries at distal sites of the vascular tree.

Prevalence of MAC is high in patient with diabetes mellitus (DM) and end stage renal diseases (ESRD). In these pathological conditions MAC is a strong prognostic marker of cardiovascular mortality. MAC can be detected by measurement of the ankle brachial index (ABI) . High ABI (* 1.30) is suggestive for MAC.

We recently analysed the ABI of patients included in the SCARPA study for atherosclerosis in hemophilia. Unexpectedly, we found an ABI *1.30 in 48.4% of hemophilia patients (n=69). This could not be explained by known risk factors as DM or low estimated glomerular filtration rate (eGFR). There is no literature on high ABI in hemophilia patients. Furthermore high ABI is rare in the general population (prevalence about 0,5%). Therefore these findings need further exploration.

First, we want to repeat measurements to confirm our data. To improve reliability of data toe brachial index (TBI) will be calculated as well in patients with ABI * 1.3, since digital arteries are usually unaffected by medial calcification, so in case of MAC ABI is high and TBI should be normal.

Study objective

The primary objective will be the prevalence of medial arterial calcification, defined as an ABI * 1.3 and a TBI > 0.7, among hemophiliacs compared with non-hemophiliacs matched by sex and age.

Study design

Cross- sectional single centre study

Study burden and risks

Measurements will take place immediately after a regular doctor visit. Additional visits to the hospital are not necessary.
Patient are requested to complete a questionnaire on cardiovascular risk factors. Measurement of ABI and TBI are non- invasive and painless. Participants may experience some discomfort when blood pressure cuffs are inflated.
The burden exist of time and sampling of 2 tubes of blood. The participants will not have immediate benefit from this observational study .
In controls no blood will be drawn. Besides, no TBI will be measured, as no high ABI is expected in healthy controls.

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:
Hemophilia A or B
Males, age * 18 years
Written informed consent for study participation;Controls:
Males, age * 18 years
Written informed consent for study participation

Exclusion criteria

Patients:
History of peripheral artery occlusive disease.
Patients with ESRD , defined as eGFR < 60 ml/ min, calculated according to the Modi*cation of Diet in Renal Disease formula.
Patients with diabetes mellitus.;Controls:
History of peripheral artery occlusive disease.
History of renal insufficiency
History of diabetes mellitus

Study design

Design

Study type: Observational 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):	22-04-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	11-03-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	14-03-2017
Application type:	Amendment
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

ID: 20634
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51599.042.14
OMON	NL-OMON20634