

Medial arterial calcification in patients with haemophilia

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20634

Source

Nationaal Trial Register

Brief title

MIRACLE

Health condition

Hemophilia patients
Vascular calcification
Ankle brachial index

Sponsors and support

Primary sponsor: Universitair medisch centrum Groningen

Source(s) of monetary or material Support: Pfizer

Intervention

Outcome measures

Primary outcome

Ankel brachial index

Toe brachial index

Secondary outcome

- Blood pressure, weight, height, waist circumference
- Data related to cardiovascular risk factors will be obtained by a standardised questionnaire.
- Severity of haemophilia, bleeding events.
- Total cholesterol, LDL-, and HDL- cholesterol, triglycerides, glucose, HbA1c, creatinine, alkaline phosphatase, calcium, phosphate, albumin.

Study description

Study objective

In hemophilia patients arterial hypertension is more common than in the general population. The cause of this increased prevalence is unknown. Recent studies on atherosclerosis in hemophilia focused on intima lesions. However, arterial calcification may affect the media as well. Medial arterial calcification (MAC) leads to concentric media thickening and stiffening of the arterial wall. Since arterial stiffness is an important contributor to arterial hypertension, MAC and consequently arterial stiffness may be more prevalent in hemophiliacs, and this may explain the high rate of systolic hypertension. MAC can be detected by measurement of the ankle brachial index. There are no reports on MAC in hemophilia.

Study design

single visit

Intervention

Single measurement of ankle brachial index and toe brachial index.

Contacts

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Eligibility criteria

Inclusion criteria

- Hemophilia A or B
- Males, adults
- Written informed consent for study participation

Exclusion criteria

- History of peripheral artery occlusive disease.
- History of ESRD , defined as $eGFR < 60$ ml/ min, calculated according to the Modification of Diet in Renal Disease formula.
- History of Diabetes Mellitus.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-08-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	31-07-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44851
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5145
NTR-old	NTR5284
CCMO	NL51599.042.14
OMON	NL-OMON44851

Study results