MRI vessel wall characteristics of peripheral arteries and arterial stiffness in hemophilia patients

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23588

Source Nationaal Trial Register

Health condition

Hemophilia Vascular calcification Media sclerosis Peripheral arteries Arterial stiffness

Sponsors and support

Primary sponsor: University Medical Center Groningen **Source(s) of monetary or material Support:** Pfizer

Intervention

Outcome measures

Primary outcome

1. Peripheral artery MRI characteristics (wall thickness, media thickness and stiffness) in hemophilia patients with a normal ankle brachial index and in hemophilia patients with a high

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ankle brachial index.

2. Carotid-(right) femoral pulse wave velocity and carotid-(left) radial pulse wave velocity in both groups.

Secondary outcome

1. Relation between vessel wall characteristics, arterial stiffness and traditional cardiovascular risk factors.

2.Relation between vessel wall characteristics, arterial stiffness and severity of haemophilia.

Study description

Background summary

Background

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 and intimal calcifications often coincide and have pathophysiologic processes in common. Clinical consequences differ, but are relevant in both types of calcification Until now, studies on atherosclerosis in patients with hemophilia focused on intimal lesions. There are no reports on medial lesions.

Hypothesis

In hemophilia patients arterial hypertension is more common than in de general population. The cause of this increased prevalence is unknown. Medial arterial calcification (MAC) leads to concentric media thickening and stiffening of the arterial wall. Arterial stiffness is an important contributor to arterial hypertension. Therefore, MAC and consequently arterial stiffness may be more prevalent in hemophiliacs, and this may explain the high rate of systolic hypertension.

Objective:

The objective of the study is to analyze and compare morphological and functional vessel

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wall parameters of peripheral arteries between hemophilia patients with an ankle- brachial index \geq 1.3 and hemophilia patients with a normal ankle- brachial index (0.9-1.3)

Study objective

The most common cardiovascular risk factor in hemophilia patients is arterial hypertension, which is also more common in this group than in the general population. Since arterial stiffness is an important contributor to arterial hypertension, vascular calcifications of the media and consequently arterial stiffness may be more prevalent in hemophiliacs.

Study design

single visit

Intervention

Subjects will remain in our study centre for no longer than four hours. MRI scanning will be performed, followed by analysis of pulse wave velocity. Next blood will be drawn and measurement of height, weight will be performed. Patients will be asked to complete a questionnaire about cardiovascular risk factors.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- 1. Hemophilia A and B patients
- 2. Written informed consent for study participating
- 3. Males, 18 years and older
- 4. Documented ABI >0.9

Exclusion criteria

1. Patients with symptomatic atherosclerotic disease or history of arterial thrombotic events.

2. Patients with chronic kidney disease (CKD), defined as eGFR < 60 ml/min, calculated according to the Modification of Diet in Renal Disease formula.

3. Patients with diabetes mellitus, defined as any history of diabetes or current diabetes (diagnosed by HbA1c iÝ 6.5% according to the American Diabetes Association diagnostic criteria).

4. Patients with any contraindication to MRI (pacemaker or claustrophobia).

Study design

Design

Study type:Observational non invasiveIntervention model:OtherControl: N/A , unknownOther

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-03-2016

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Enrollment:

Type:

40

Anticipated

Ethics review

Not applicable Application type:

Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 41839 Bron: ToetsingOnline Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5329
NTR-old	NTR5438
ССМО	NL52159.042.15
OMON	NL-OMON41839

Study results

Summary results

n.a.