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

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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,...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23588

Bron
Nationaal Trial Register

Aandoening

Hemophilia
Vascular calcification
Media sclerosis
Peripheral arteries
Arterial stiffness

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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.

Onderzoeksopzet

single visit

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Hemophilia A and B patients

2. Written informed consent for study participating

3. Males, 18 years and older

4. Documented ABI >0.9

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 ¡Ý 6.5% according to the American Diabetes Association diagnostic criteria).

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2016
Aantal proefpersonen:	40

Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41839
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
n.a.