Hemophilia and Atherosclerotic Plaque Imaging: an exploratory study

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We hypothesize that patients with hemophilia who have atherosclerotic plaques in the carotid arteries, have a higher prevalence of intraplaque hemorrhage compared to subjects with a normal bleeding phenotype, and thereby a higher proportion of...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23229

Bron
NTR

Verkorte titel
MAGICAL study (Magnetic Resonance Imaging of Carotid Arteries in Hemophilia Patients)

Aandoening

hemophilia
atherosclerosis
3T MRI
Plaque vulnerability

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective is to assess carotid artery plaque constitution in terms of intraplaque hemorrhage and plaque burden (thickness) as measured with 3T MRI in both hemophilia patients and control patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Synopsis

Title

Hemophilia and Atherosclerotic Plaque Imaging: an exploratory study

Background

We showed that hemophilia patients with and without obesity have the same degree of atherosclerosis compared to control subjects. In clinical practice, we indeed see an increasing amount of patients with stroke and myocardial infarction. There is increasing evidence that vulnerability of the atherosclerotic plaque greatly increases the risk of rupture of the plaque, thereby inducing an ischemic event. One of the most important contributors to the vulnerability of the plaque is intraplaque hemorrhage. Patients with hemophilia have a lifelong increased bleeding tendency due to the deficiency of clotting factor. It is unknown whether hemophilia patients are also at increased risk of bleeding into atherosclerotic plaques. Magnetic resonance imaging (MRI) enables transverse 3-dimensional imaging of atherosclerosis at high resolution with excellent interscan reproducibility. 3-Tesla MRI visualizes the carotid artery wall and the constitution of the atherosclerotic plaque. It quantifies plaque volume and is able to assess bleeding in the plaque. The great advantage of MRI compared to CT-scan is the fact that MRI carries a no ionizing radiation exposure. Recent magnetic resonance studies have indicated that intraplaque hemorrhage may accelerate plaque progression and play an important role in plaque destabilization. An in-vivo study showed that intraplaque hemorrhage also has considerable impact on plaque stress and strain conditions, which further increases the risk of rupture.

Study objective: The primary objective is to assess carotid artery plaque constitution in terms of
intraplaque hemorrhage and plaque burden (thickness) as measured with 3T MRI in both hemophilia
patients and control patients.

Study design: cross-sectional study, mono center study (University Medical Center Groningen).

Study population: 40 patients with documented cardiovascular risk factors: 20 hemophilia patients
and 20 control patients, recruited form the outpatient clinic of vascular medicine.

-Study procedures

In all subjects blood will be drawn to assess glucose and lipid levels; and a physical examination including measurement of weight, length, and blood pressure measurement will be performed. MRI scans of the carotid artery will be performed with a 3.0-T scanner using a dedicated coil.

-The medical ethics committee of the University Medical Center Groningen has approved the study. The study will be performed under GCP conditions.

Doel van het onderzoek

We hypothesize that patients with hemophilia who have atherosclerotic plaques in the carotid arteries, have a higher prevalence of intraplaque hemorrhage compared to subjects with a normal bleeding phenotype, and thereby a higher proportion of vulnerable plaques compared to non-hemophilic patients with atherosclerotic plaques.

Onderzoeksopzet

Single MRI measurement

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Hemophilia A or B patients:

1. Males, 18 years and older

2. Presence of cardiovascular risk factors, including an age ≥ 50 years.

Controls:

1. Males, 18 years and older

2. Presence of cardiovascular risk factors, including an age ≥ 50 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients and controls:

Patients with symptomatic carotid atherosclerotic disease.

History of allergic reaction to gadolinium or other contrast medium (very rare)

History of claustrophobia

History of severe renal failure (estimated glomerular filtration rate ≤ 45 ml/min)

Presence of cardiac pacemakers

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2017
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-05-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46894
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5134
NTR-old	NTR5274
CCMO	NL46624.042.13
OMON	NL-OMON46894

Resultaten