# Hemophilia and Atherosclerotic Plaque Imaging: an exploratory study

No registrations found.

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

## Summary

### ID

NL-OMON23229

**Source**
NTR

**Brief title**
MAGICAL study (Magnetic Resonance Imaging of Carotid Arteries in Hemophilia Patients)

**Health condition**

hemophilia
atherosclerosis
3T MRI
Plaque vulnerability

### Sponsors and support

**Primary sponsor:** UMCG
**Source(s) of monetary or material Support:** Pfizer

### Intervention

### Outcome measures

**Primary outcome**

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.

### Secondary outcome

To analyze whether the severity of hemophilia affects plaque composition and whether traditional cardiovascular risk factors are important mediators

## Study description

### Background summary

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.

**Study objective**

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.

**Study design**

Single MRI measurement

**Intervention**

none

# Contacts

**Public**
Vascular Medicine - University Medical Center Groningen

Hilde Hop
Hanzeplein 1

Groningen 9713 GZ
The Netherlands
Tel: +31503612943
**Scientific**
Vascular Medicine - University Medical Center Groningen

Hilde Hop
Hanzeplein 1

Groningen 9713 GZ
The Netherlands
Tel: +31503612943

# Eligibility criteria

## Inclusion criteria

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.

## Exclusion criteria

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

# Study design

## Design

| | |
|---|---|
| Study type: | Observational non invasive |
| Intervention model: | Parallel |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-11-2017 |
| Enrollment: | 40 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 21-05-2015 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 46894
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

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

# Study results