Hemophilia and Atherosclerotic Plaque Imaging

Published: 06-02-2014
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The primary outcome 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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON46894

Source
ToetsingOnline

Brief title
Hemophilia and Atherosclerotic Plaques

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis, hemophilia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Pfizer,unrestricted grant van Pfizer

Intervention

Keyword: Atherosclerosis, Hemophilia, MRI scan, Plaque constitution

Outcome measures

Primary outcome

The primary outcome is the plaque constitution in terms of intraplaque hemorrhage and plaque burden as measured with 3T MRI in both hemophilia patients and patients and controls

Secondary outcome

Secondary parameters are differences in endothelial wall function and plaque components (calcification, necrotic core) between the patient and control group.

Furthermore, the relation between plaque composition and severity of haemophilia and traditional cardiovascular risk factors will be analysed.

Study description

Background summary

Patients with hemophilia have a lifelong increased bleeding tendency due to the deficiency of factor VIII. We recently showed that hemophilia A patients with obesity have the same degree of atherosclerosis compared to obese 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.It is unknown whether hemophilia patients are at increased risk of vulnerable 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 low radiation exposure. In addition, it has been shown that 3T-MRI can also visualise endothelial shear stress, an important marker for arterial stiffness and remodelling.
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 outcome 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 case-control study

Study burden and risks

The study is associated with a low burden. Subjects will remain in our study centre for no longer than three hours. MRI scanning caries no ionizing radiation exposure. A MRI constrast agant (Dotarem) will be injected intravenously. Dotarem has a risk on serious harm. In order to minimize these risks, patients with kidney failure or a history of allergic reaction to contrast media will be excluded. Participants might experience some physical discomfort after administration of Dotarem.
Contrast enhanced MRI- scanning increases the quality of images. The main components of the plaque can only be distinguished accurately by using contrast.
Further research is necessary for a better understanding of cardiovascular disease in haemophilia. Results of this study may lead to new insights on the pathophysiology of atherosclerosis in haemophilia patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Study population:;1. Hemophilia A or B patients
2. Males, 18 years and older
3. Presence of cardiovascular risk factors, including an age of 50 years and more;Controls:
1. Males, 18 years and older
2.. Presence of cardiovascular risk factors, including an age of 50 years and more

Exclusion criteria

Study population and controls:
1. Symptomatic carotid atherosclerotic disease
2. History of allergic reaction to gadolinium (very rare)
3. History of claustrophobia
4. History of severe renal failure (estimated glomerular filtration rate - < 45 ml/min)
5. Presence of cardiac pacemaker;Controls:
Use of anticoagulation

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	06-02-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	09-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	07-03-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23229
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46624.042.13
OMON	NL-OMON23229