

Coronary artery calcification measured with multi detector-row computed tomography in patients with hemophilia A

Published: 15-09-2009

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To investigate whether patients with hemophilia A develop less coronary artery atherosclerosis as compared to non-hemophilic males.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON35314

Source

ToetsingOnline

Brief title

Coronary artery calcification in hemophilia patients

Condition

- Coronary artery disorders
- Blood and lymphatic system disorders congenital

Synonym

atherosclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: CSL Behring

Intervention

Keyword: atherosclerosis, calcification, hemophilia, MDCT

Outcome measures

Primary outcome

Coronary artery calcification score (Agatston score).

Secondary outcome

NA.

Study description

Background summary

Several cohort studies reported a reduced mortality due to ischemic heart disease in hemophilia patients as compared to the general population. One explanation could be that hemophilia patients develop less atherosclerosis than non-hemophilic males. Although several study groups investigated this hypothesis, it remains unclear whether the deficiency of factor VIII or IX exerts a protective effect on the development of atherosclerosis.

Study objective

To investigate whether patients with hemophilia A develop less coronary artery atherosclerosis as compared to non-hemophilic males.

Study design

In this cross-sectional study, coronary artery calcification, which is a measure of coronary artery atherosclerosis, will be assessed in hemophilia A patients with Multi Detector-Row Computed Tomography, a non-invasive vascular imaging technique. Coronary artery calcification in hemophilia A patients will be compared with coronary artery calcification in non-hemophilic males.

Study burden and risks

This study will contribute to the knowledge about the role of factor VIII and the intrinsic coagulation pathway in atherogenesis, can help us understand this

process in further detail, and may eventually lead to new prevention strategies or medical treatments in patients with hemophilia, and possibly in patients without hemophilia. However, the results of this study will probably not be directly beneficial for the participating patients. Participating hemophilia patients do benefit from their individual cardiovascular risk assessment. If cardiovascular risk factors are discovered, lifestyle changes will be advised or medical treatment will be started. Adverse events are not expected to occur in this study and radiation exposure is very low. One extra visit to the hospital is needed when participating.

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

- Patients with severe or moderate hemophilia A, ≥ 59 years

3 - Coronary artery calcification measured with multi detector-row computed tomograp ... 8-05-2025

- Non-hemophilic males from the Rotterdam Study, matched for birth year

Exclusion criteria

- Hemophilia patients or non-hemophilic males with symptomatic cardiovascular disease
- Hemophilia patients or non-hemophilic males infected with HIV
- Non-caucasian hemophilia patients or non-hemophilic males

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):	10-11-2009
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO	
Date:	15-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	22-02-2010

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-04-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-09-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL26472.041.09