The incidence of endothelial dysfunction and atherogenesis in hemophilia patients with obesity: the Idaho-study

Published: 27-05-2008
Last updated: 10-05-2024

Are overweight or obese patients protected against atherosclerosis when suffering from haemophilia A? Is this association influenced by the severity of haemophilia? When the coagulation activity increases due to obesity (and inflammation), will this...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31530

Source
ToetsingOnline

Brief title
The Idaho study

Condition

- Other condition
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
bleeders' disease, cardiovascular disease

Health condition

hemofilie, atherosclerose, endotheeldysfunctie, obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: grant (farmaceutisch bedrijf)

Intervention

Keyword: atherogenesis, endothelial dysfunction, haemophilia, obesity

Outcome measures

Primary outcome

Endothelial function and degree of atherosclerosis will be compared in the four groups. The degree of inflammation, platelet aggregation, fibrin formation, and fibrinolysis will also be assessed in the four different groups.

Secondary outcome

We will also investigate the amount of bleeding complications and analyse the influence of obesity on this outcome.

Study description

Background summary

Results of studies concerning the role of haemostasis in ischemic cardiovascular disease (CVD) indicate that hypercoagulability increases the risk of CVD, whereas hypocoagulability decreases that risk. Patients with a hereditary deficiency of clotting factor VIII (Haemophilia A) have considerable protection against myocardial infarction. In 2001, a Dutch group reported no effect of haemophilia A on intima media thickness (IMT) in the carotid and femoral artery. Subgroup analysis, however, revealed that patients with moderate or severe haemophilia had a tendency towards a thinner IMT. The group of patients with severe haemophilia was too small (n=20) to adequately address this question. However, considering the increasing life expectancy, if haemophilia patients are not protected against atherogenesis, atherosclerotic risk factors will have to be treated. Another question that arises, is whether there is an inverse association between the severity of haemophilia and atherosclerosis? A larger study population is necessary to further analyse the matter. As is the case in the general population, in haemophiliac patients

there is an increasing prevalence of overweight (BMI>25 kg/m2) and obesity (BMI>30 kg/m2), which may predispose to atherosclerotic cardiovascular disease. As obesity is associated with an increased procoagulant activity, this can lead to atherosclerosis-related morbidity, like hypertension and peripheral vascular disease. A potential advantage for an overweight or obese haemophiliac patient may be a less severe bleeding phenotype.

Study objective

Are overweight or obese patients protected against atherosclerosis when suffering from haemophilia A? Is this association influenced by the severity of haemophilia? When the coagulation activity increases due to obesity (and inflammation), will this lead to a decreased bleeding tendency?

Study design

This multicenterd, case-control study will include patients with severe, moderate and mild types of haemophilia A, that either have obesity or a normal bodymass. Healthy sex-, age- and BMI- matched individuals will serve as controls. All subjects will receive a standardized questionnaire and will, after an overnight fast, be invited to come to the department of Vascular Medicine of the study centres for the drawing of blood, waist to hip ratio, BMI and bloodpressure measurements. Additionally they will undergo non-invasive ultrasonography.

Study burden and risks

None of the procedures the subjects will undergo are invasive and the participation will consist of a one day visit to our study centre. Subjects will receive a standardized questionnaire at home prior to their visit to our study centre and they will be asked to come after an overnight fast. We will measure BMI, waist to hip ratio and blood pressure (three times). We will also draw blood samples. In addition, we will perform non-invasive carotid IMT and brachial FMD ultrasound measurements.

Contacts

Public
Academisch Medisch Centrum

meibergdreef 9
1105 AZ Amsterdam
NL
Scientific

Academisch Medisch Centrum

meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Haemophilia A patients (obese or normal weight)
All haemophilia patients are male
All subject are 18 years or older

Exclusion criteria

pre-existing cardio-vascular disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	160
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL21074.018.07