Variability in bleeding phenotype in patients with hemophilia A.

Published: 04-01-2010
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To investigate the relation of platelet responsiveness and systemic platelet activity to phenotype in patients with severe hemophilia A.

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

Summary

ID

NL-OMON33172

Source
ToetsingOnline

Brief title
Variability in phenotype in hemophilia A

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Blood and lymphatic system disorders congenital

Synonym
coagulation disorder, hemophilia A

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Factor VIII, Hemophilia A, phenotype

Outcome measures

Primary outcome

To investigate the association of platelet responsiveness (EC50 of CRP stimulation, iloprost inhibition, and ADP stimulation) with clinical phenotype in patients with severe hemophilia A.

Secondary outcome

To investigate the association of systemic platelet activation with clinical phenotype in patients with severe hemophilia A.

Study description

Background summary

Large variability in phenotype has been observed in patients with severe hemophilia A (<1% residual factor VIII activity), which indicates that additional factors influence bleeding phenotype. This variability can not be explained by levels of coagulation proteins. Platelet responsiveness and systemic platelet activity might be these additional factors.

Study objective

To investigate the relation of platelet responsiveness and systemic platelet activity to phenotype in patients with severe hemophilia A.

Study design

Platelet responsiveness to XL-CRP stimulation, Iloprost inhibition, and ADP stimulation will be measured in freshly collected whole blood. Plasmamarkers of platelet activity will be measured in plasma. The remaining material will be saved (-80 degrees).

Study burden and risks

For this study an amount of 7.5 ml of blood will be drawn per patient at the van Creveldkliniek. If possible this visit will be combined with a regular visit to the van Creveldkliniek.
The results of this study will not be directly beneficial for the participating patients. This study will improve to the knowledge about the role of blood platelets in the variability in bleeding phenotype in hemophilia A.

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

Severe hemophilia A
Most mild or most severe phenotype.
Age 18 years or older

Exclusion criteria

Alcohol abuse.
Use of medication which is known to influence platelet function
Drug use (cannabis).

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):	22-12-2010
Enrollment:	84
Type:	Actual

Ethics review

Approved WMO

Date:	04-01-2010
Application type:	First submission
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	NL27236.041.09