International study on etiology of inhibitors in patients with a moderate or mild form of hemophilia A, influences of immunogenetic and hemophilia treatment factors.

Published: 23-06-2008
Last updated: 07-05-2024

The aims of this project are:A. To describe the incidence of inhibitor formation in moderate/mild hemophilia A patients.B. To identify clinical and genetic factors that induce inhibitor formation in patients with moderate/mild hemophilia A.C. To...

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

Summary

ID

NL-OMON32171

Source
ToetsingOnline

Brief title
INSIGHT

Condition

- Other condition

Synonym
bleeding disorder, hemophilia A

Health condition

stollingsstoornissen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: CSL Behring,unrestricted research grant van farmaceutisch bedrijf

Intervention

Keyword: Hemophilia A, Inhibitor, Mild/moderate, Risk factors

Outcome measures

Primary outcome

- The incidence of inhibitor development in mild/moderate hemofilia A.

- Clinical and genetic risk factors that promote inhibitor development in

mild/moderate hemofilia A.

- T-cell epitopes in patients with mild/moderate hemophilia A and inhibitory

antibodies.

Secondary outcome

Not applicable

Study description

Background summary

The development of inhibiting antibodies (inhibitors) represents a major challenge in the management of hemophilia. In patients with moderate/mild hemophilia A the inhibitor incidence seems to be rising. Since the prevalence of moderate/mild hemophiliacs is relatively high, the clinical impact of this problem is substantial. Several investigators have suggested that extensive factor VIII replacement in surgical patients may increase the risk of inhibitor development. However, a number of important questions remain unanswered. It is important to know which clinical and genetic factors lead to inhibitor development, because this may ultimately help reduce the risk by preventive

measures.

Study objective

The aims of this project are:

A. To describe the incidence of inhibitor formation in moderate/mild hemophilia A patients.

B. To identify clinical and genetic factors that induce inhibitor formation in patients with moderate/mild hemophilia A.

C. To characterize T cell epitopes in patients with moderate or mild hemophilia A and inhibitory antibodies.

Study design

This project consists of three international multicenter studies:

A. A cohort study to describe the incidence of inhibitor formation in moderate/mild hemophilia A patients.

B. A case-control study to identify clinical and genetic factors that induce inhibitor formation in patients with moderate/mild hemophilia A.

C. Experimental study to characterize T cell epitopes in patients with moderate or mild hemophilia A and inhibitory antibodies.

Study burden and risks

The only burden of the case-control and experimental study is the drawing of one extra tube of blood at a moment of regular blood sampling for clincial reasons. This is in proportion to the potential value of the study.
The results of the study may be relevant in the future for prevention of inhibiting antibodies in patients with mild/moderate hemophilia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

mild/moderate hemophilia A (factor VIII 2-40%)

Exclusion criteria

severe hemophilia A (factor VIII <2%)

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:	Pending
Start date (anticipated):	01-11-2012
Enrollment:	60
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	NL21605.018.08