Does physical exercise increase clotting factor VIII levels in patients with moderate or mild haemophilia A ?

Published: 12-05-2009
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The aim of this study is to investigate whether exercise changes FVIII levels in patients with moderate and mild haemophilia.

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

Summary

ID

NL-OMON35196

Source
ToetsingOnline

Brief title
Exercise in Haemophilia A Patients

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
FVIII deficiency, haemophilia A

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: overgeblevende fondsen van post-marketing surveillance studie

Intervention

Keyword: Factor VIII, increase, physical activity

Outcome measures

Primary outcome

The primary endpoint of this study is the change in FVIII levels because of exercise in moderate and mild haemophilia A patients.

Secondary outcome

The secundary endpoints of this study are von Willebrand factor, von Willebrand propeptide and t-PA before and 10 minutes after exercise in moderate and mild haemophilia A patients.

Study description

Background summary

Besides the fact that exercise is part of a healthy lifestyle, it is shown that exercise increases levels of factor VIII (FVIII) in healthy subjects. It has been suggested that moderate and mild haemophilia A patients are also able to increase their endogenous FVIII levels during exercise. If FVIII increases in moderate and mild haemophilia A patients during exercise, patients might reduce the risk of bleeding episodes. This might have positive implications towards docters'recomendations concerning sports and subsequently increase quality of life.

Study objective

The aim of this study is to investigate whether exercise changes FVIII levels in patients with moderate and mild haemophilia.

Study design

In this trial, coagulation components of 20 patients with FVIII levels from 1-20% will be measured before and 10 minutes after a standardised incremental exercise test, till volitional exhaustion, on an electronically braked cycle ergometer. Blood samples will be drawn according to the Van Creveldkliniek,

haemophilia treatment centre protocol. FVIII levels, von Willebrand factor (vWf), propeptide, bloodtype and t-PA will be tested in one batch, via standard laboratory protocol.

Study burden and risks

Participants will be subjected to 1 extra venapuncture and an incremental exercise test. Their routine visit will be extended by approximately 30 minutes. the risk is considered to be minimal. A certified and experienced nurse will draw bloodsamples following haemophilia treatment center protocol.

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

• Haemophilia A
• FVIII activity 1-20%.
• 18-40 years of age
• Male
• Normally active
• Able to complete the exercise test without great difficulty

Exclusion criteria

• History of inhibitors
• No access to standard haemophilia care since birth (e.g. immigration from other country)
• Joint damage which complicates riding a bicycle
• A known medical condition that may deteriorate during strenuous physical activities

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2009
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	12-05-2009

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-09-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-05-2010
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	NL26839.041.09