Clinical validation of Factor VIII allo-antibody assays in patients with hemophilia A. The correlation of factor VIII antibodies, measured with different assays, on factor VIII survival in patients with severe haemophilia A.

Published: 28-07-2011
Last updated: 15-05-2024

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

Summary

ID

NL-OMON31749

Source
ToetsingOnline

Brief title
Validation of F VIII antibody assays in hemophilia A patients

Condition

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

Synonym
Haemophilia A

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Wyeth

Intervention

Keyword: Antibody, Assay, Factor VIII, Pharmacokinetics

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Study burden and risks

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Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 8
6525 GA Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 8
6525 GA Nijmegen
NL

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

Inclusion criteria for patients with severe hemophilia A without inhibitors:
1) Phenotype less than 1% factor VIII activity
2) No history of an inhibitor
3) Normal response to Factor VIII infusion during bleeding episodes
4) Normal recovery
5) No recent change in bleeding pattern
6) No Factor VIII infusion for minimally 72 hours before start of the study.;Inclusion criteria for patients with severe hemophilia A with inhibitor or at high risk of having an inhibitor:
1) Phenotype less than 1% factor VIII activity

2) Diminished response to Factor VIII compared to past performance,
Or: Low recovery
Or: More frequent bleedings and/or a different bleeding pattern
Or: higher need for Factor VIII substitution than before
3) No factor VIII infusion for minimally 72 hours before start of the study

Exclusion criteria

Exclusion criteria for severe hemophilia A patients with or without Factor VIII inhibitors:
1) Known allergy to plasma proteins
2) Fever (higher than 38 °C)
3) Clinical indication of liver cirrhosis (echo graphic indication, enlarged spleen, enlarged liver, decreased platelet count, elevated ALAT/ ASAT levels
4) Hepatitis C recently treated with interferon (washout 6 months)
5) HIV positive
6) Medication:
NSAIDs (non-steroid anti-inflammatory drugs)
Ascal
Clopidogrel
Antimicrobial medication
Thyroid inhibitors
Selective serotonin re-uptake inhibitors.
7) Hb levels less than 8.0 mmol/l
8) Platelet counts less than 50*109/ltr

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2011
Enrollment:	50

Type:	Actual

Ethics review

Approved WMO Date:	28-07-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23098
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL19146.091.08
OMON	NL-OMON23098