Rare Bleeding disorders in the Netherlands

Published: 19-09-2017
Last updated: 13-04-2024

To describe the epidemiology, bleeding tendency, laboratory parameters, quality of life and genetics of all known patients in the Netherlands with rare bleeding disorders (RBD). In addition, the study aims to examine the relationship between...

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

Summary

ID

NL-OMON47773

Source
ToetsingOnline

Brief title
RBiN

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
a2-antiplasmin or PAI-1. Rare bleeding disorders, deficiency of factor I, II, V, V&VIII, VII, X, XI, XIII

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Blood Coagulation Disorders, Genotype, Phenotype, Quality of life

Outcome measures

Primary outcome

Description of the clinical phenotype, laboratory phenotype, genotype and

quality of life of patients with rare bleeding disorders

Secondary outcome

not applicable

Study description

Background summary

Rare Bleeding Disorders (deficiencies of fibrinogen, factor II, V, V&VIII, VII, X, XI, XIII, α2-antiplasmin or plasminogen activator inhibitor 1) have a disperse clinical presentation, bleeding scores, bleeding episodes, health-related quality of life and laboratory parameters. Moreover, there is no clear match between phenotype and genotype.

Study objective

To describe the epidemiology, bleeding tendency, laboratory parameters, quality of life and genetics of all known patients in the Netherlands with rare bleeding disorders (RBD). In addition, the study aims to examine the relationship between clinical and laboratory phenotype and genotype.

Study design

Cross-sectional multicentre observational study

Study burden and risks

Minimal risk due to one time venepuncture

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
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

Rare bleeding disorder
Age 1-99

Exclusion criteria

No informed consent
Residency outside of the Netherlands

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2017
Enrollment:	246
Type:	Actual

Ethics review

Approved WMO Date:	19-09-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-01-2018
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL61027.091.17