

Haemophilia in the Netherlands 6

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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-OMON49798

Source

ToetsingOnline

Brief title

HiN-6

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym

factor VIII deficiency/factor IX deficiency, Haemophilia

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Haemophilia, Inhibitors, Quality of health care, Quality of life

Outcome measures

Primary outcome

Presence of disease-related co-morbidities, health-related quality of life, quality of care, self-reported bleeding severity, self-reported joint function and the presence of inhibitors, non-neutralizing antibodies and immunological markers.

Secondary outcome

Not applicable

Study description

Background summary

There is little information on the current health status of the Dutch haemophilia population, especially ageing patients, HIV/HCV patients and inhibitor patients. In addition, quality of life may be reduced in some persons with haemophilia (PWH) despite similar levels of physical health. Furthermore, differences in clinical phenotypes have been described in patients with comparable coagulation factor activities. Lastly, inhibitor formation is still an important complication in haemophilia treatment, a better understanding is needed about the mechanisms that lead to inhibitor formation.

Study objective

The purpose of the HiN-6 study is:

- (1) To describe the health status of the Dutch haemophilia population, with special focus on viral infections, inhibitor development and age-related co-morbidities.
- (2) To gain insight into the health-related quality of life of PWH.
- (3) To gain insight into the quality of care of PWH.
- (4) To explain the variability in clinical phenotype among PWH.
- (5) To gain insight into the mechanisms underlying the humoral and cellular immune response to FVIII.

Study design

The HiN-6 study will consist of both cross-sectional and longitudinal observational studies, according to the specific research objective. Some of the collected patient material and clinical data will be used to set up a biobank. Data will be collected from each participant's medical record using case report forms, through questionnaires filled in by each participant, by blood sampling and by urine sampling.

Study burden and risks

The participants' burden consists of 1 or 2 blood draws, one urine collection and filling in a questionnaire. No direct benefit is expected from participation in this study. Participation in this study may have benefits for future patients with haemophilia.

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

- Men with severe, moderate, mild congenital haemophilia A or B that are registered at one of the haemophilia treatment centres in the Netherlands.
- Written informed consent before data collection and sampling blood/urine.
- Male patients with congenital haemophilia A or B who underwent liver transplantation in the past (irrespective of their endogenous clotting factor levels)
- All currently deceased male haemophilia A or B patients that participated in the HiN-5 questionnaire in 2001

Exclusion criteria

- Female carriers of haemophilia A or B
- Symptomatic carriers of haemophilia A or B
- Patients with acquired haemophilia.
- Patients with reduced FVIII levels due to Von Willebrand disease.
- Inability to obtain informed consent from patients older than 12 years of age.
- No informed consent before data collection and sampling blood/urine.

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): 14-05-2018

Enrollment: 1250

Type: Actual

Ethics review

Approved WMO

Date: 24-01-2018

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

Approved WMO

Date: 29-08-2019

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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

CCMO

ID

NL59114.058.17