Arthropathy in patients with congenital severe and moderate severe von Willebrand disease

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To assess the prevalence, severity and impact of arthropathy in patients with moderate or severe VWD and a history of documented DDAVP or clotting factor concentrate treatment for joint bleeds. To compare arthropathy in these patients to age, FVIII…

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

Summary

ID

NL-OMON39851

Source
ToetsingOnline

Brief title
Willebrand arthropathy study (WAS)

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Joint disorders

Synonym
athropathy, joint damage

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: CSL Behring,farmaceutische industrie

Intervention

Keyword: Arthropathy, Joint bleed, Von Willebrand Disease

Outcome measures

Primary outcome

Existence of arthropathy: the number and percentage of patients with arthropathy among the different patient groups.

Severity of arthropathy: separate and cumulative scores of HJHS and Pettersson.

Impact of arthropathy on physical functioning and participation: time to complete the figure 8 walking test, separate and cumulative scores of (Ped)HAL and IPA questionnaires.

Impact on quality of life: separate and cumulative scores of D-AIMS2-affect and MPQ-DLV questionnaires.

Secondary outcome

Influence of the severity of the coagulation defect on the existence, severity and impact of arthropathy

Number and sites of affected joints

Quantitative use of desmopressin and coagulation factors in relation to the existence of arthropathy

Prophylactic use of coagulation factors in relation to the existence of arthropathy

Influence of age, BMI, quantitative use of desmopressin and coagulation factors, surgical interventions and sports activities on the existence,

severity and impact of arthropathy

Study description

Background summary

Little is known about the severity and impact of arthropathy in patients with severe and moderate severe von Willebrands disease (VWD).

Study objective

To assess the prevalence, severity and impact of arthropathy in patients with moderate or severe VWD and a history of documented DDAVP or clotting factor concentrate treatment for joint bleeds. To compare arthropathy in these patients to age, FVIII and sex matched VWD patients without documented joint bleeds and to age and FVIII matched patients with haemophilia A.

Study design

Cross-sectional multicenter cohort study coordinated from the Van Creveldkliniek (VCK) of the University Medical Center Utrecht (UMCU).

Study burden and risks

This study will be the first to assess severity and impact of arthropathy in patients with VWD. The total amount of time required is minimum 1 hour and 3 hours for the visit and measurements which will be combined with regular visits if possible. Filling in the questionnaires will take approximately 60 minutes of extra time for adult participants and 10 minutes for subjects <18 years. The participating patients will not benefit directly from participation. However, when arthropathy is found, the physiotherapist can give advice or refer patients for further treatment on their request. Furthermore, better understanding of arthropathy in WVD can lead to future preventive strategies and improvement in information to young patients facing possible future consequences of their disease. Risks imposed by participation are considered negligible. However, because subjects<18 years can participate, there is a minor increase over minimal risk.

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

Patients with moderate or severe VWD who participated in the *Willebrand in Nederland* (WiN) study and who reported treatment with coagulation factor or desmopressin for 1 or more joint bleeds (patients)
Patients with moderate or severe VWD who participated in the *Willebrand in Nederland* (WiN) study and did not report treatment with coagulation factor or desmopressine for 1 or more joint bleeds (controls)
Patients with moderate or severe VWD who are currently treated at a haemophilia treatment centre in the Netherlands with or without a history of coagulation factor or desmopressin for 1 or more joint bleeds
Comprehension of the Dutch written and spoken language

Exclusion criteria

Inability of the patient or the patients parents to give informed consent
Active joint pathology (i.e. recent episode of joint haemorrhage)
Restricted motion of an ankle, knee or elbow joint for another medical reason
No medical file available
Age 4 years or younger

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-08-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	18-09-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-09-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO Date:	26-11-2014
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

ID: 24768
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL38989.041.12
OMON	NL-OMON24768