Joint bleeds in Von Willebrand disease: Impact on joint integrity, -function and daily life.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24768

Source
Nationaal Trial Register

Brief title
Willebrand Artropathy Study

Health condition

patients with moderate or severe Von Willebrand disease

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Grant from CSL Behring

Intervention

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

Study description

Background summary

Cross sectional multicenter cohort study that investigates the prevalence, severity and impact of arthropathy in patients with moderate and severe Von Willebrand disease and documented treatment of joint bleeds with desmopressin or clotting factor concentrate compared to moderate and severe VWD patients without such documented joint bleed treatment.

Study objective

the severity and impact of arthropathy in patients with VWD could be significant

Study design

one assessment no follow up assessments planned

Intervention

assessment of joint damage, joint pain and related functional and social impairment by 4 questionnaires for adults, 1 for children, 1 physical joint examination, joint X-rays and 1 functional test. The physical joint examination and functional test will be scored by an experienced physiotherapist using the Haemophilia Joint Health Score (HJHS). The functional test consists of a figure 8 walking test. X-rays will be taken of affected and contralateral joints in all participants aged>12 years and of the same joint in a matched control patient.

Contacts

Public
Van Creveldkliniek UMC Utrecht
K.P.M. Galen, van
Utrecht
The Netherlands
Scientific
Van Creveldkliniek UMC Utrecht
K.P.M. Galen, van
Utrecht
The Netherlands

Eligibility criteria

Inclusion criteria

Patients with moderate or severe VWD treated with coagulation factor or desmopressin for 1 or more joint bleeds as documented in their MF.

A similar size control group of age (< 2 years difference), FVIII and sex matched moderate or severe VWD patients who participated in the WiN study, indicated that they would like to participate in future studies, and did not report treatment for 1 or more joint bleeds and also did not have joint bleeds recorded in their MF.

Also eligible for the control group are moderate or severe VWD patients who did not participate in the WiN study and are currently treated at the haemophilia treatment centres in the Netherlands who have not been treated with coagulation factor or desmopressin for 1 or more joint bleeds and without joint bleeds treatment documented in their MF.

Exclusion criteria

Inability of the patient or the patients parents to give informed consent

A recent joint bleed without complete recovery

Restricted motion of an ankle, knee or elbow joint for another medical reason

No medical file available

Age<4 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	23-04-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39851
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4424
NTR-old	NTR4548
CCMO	NL38989.041.12
OMON	NL-OMON39851

Study results