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

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24768

Bron
Nationaal Trial Register

Verkorte titel
Willebrand Artropathy Study

Aandoening

patients with moderate or severe Von Willebrand disease

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Grant from CSL Behring

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

one assessment no follow up assessments planned

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Van Creveldkliniek UMC Utrecht
K.P.M. Galen, van
Utrecht

The Netherlands

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-08-2013
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-04-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39851
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten