Measurement of gait variability in patients with and without hemophilic arthropathy; MOVE study

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- A new sensorbased gait analysis measurement as a simple and quick diagnostic/monitoring tool to evaluate joint status and changes in gait pattern in hemophilia patients. - Possibility to detect a disturbed gait pattern in clinically asymptomatic...

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

Samenvatting

ID

NL-OMON22693

Bron
NTR

Verkorte titel
MOVE study

Aandoening

hemophilia, gait pattern, arthropathy, gaitSMART, footwear

hemofilie, looppatroon, artropathie, gaitSMART, schoeisel

Ondersteuning

Primaire sponsor: Erasmus University Medical Center, Sophia Children's Hospital, Rotterdam, the Netherlands
Overige ondersteuning: Pfizer

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Disturbed gait pattern detected with sensor based gait analysis system, defined as % of difference in range of motion, quality of gait and symmetry of gait compared to the reference population.

Toelichting onderzoek

Achtergrond van het onderzoek

PROBLEM DEFINITION: Musculoskeletal assessment is necessary to evaluate efficacy of coagulation factor replacement therapy in hemophilia. Most current tools do not integrate the global impact of multiple-joint arthropathy or muscle bleeds. A new and simple sensor based gait analysis device measures and detects changes in gait pattern. This can serve as a screening tool in hemophilia patients with and without arthropathy.

OBJECTIVE: To establish whether this system can be used to detect gait abnormalities in hemophilia patients

STUDY DESIGN: Single-center cross sectional observational study

STUDY POPULATION: Hemophilia A or B patients with all severities

FEASIBILITY OF THE PROJECT: With 300 hemophilia patients in our Hemophilia Treatment Center and an annual visit of each patient, more than 100 patients can be included.

RELEVANCE FOR CLINICAL PRACTICE

A. CONCRETE REVENUES:

1. Simple and quick diagnostic and monitoring tool to evaluate joint status

2. Possibility to detect a disturbed gait in clinically asymptomatic patients

B. IMPLEMENTATION OF RESULTS:

If this sensor based gait analysis system shows to be an effective tool, we plan to implement this type of gait analysis in our regular hemophilia care; i.e. annual analysis.

Doel van het onderzoek

- A new sensorbased gait analysis measurement as a simple and quick diagnostic/monitoring

tool to evaluate joint status and changes in gait pattern in hemophilia patients.

- Possibility to detect a disturbed gait pattern in clinically asymptomatic patients (HJHS=0)

Onderzoeksopzet

Because of the cross-sectional design of this study, every patient will be measured once. No follow-up intended.

Onderzoeksproduct en/of interventie

Gait analysis with a new, simple and quick device. The six sensors of this system will be mounted on both sides of the hip, on the lateral side of the lower limbs using straps around thigh (just below the greater trochanter) and calf (at the level of the belly of the gastrocnemius muscle). Each patient will be asked to walk at least 20 meters on his own shoes, on standardized shoes and barefoot (grip socks for hygiene). The analysis of the walking test will be done using dedicated software. The analysis will be performed on the section of the walking test where the patient is walking steadily for at least 7 strides.

A physiotherapist specialized in hemophilia care will assess the Hemophilia Joint Health Score (HJHS) on the same day as the walking test. The results of the walking test will not be available to the physiotherapist and the HJHS assessment will not be available to the walking test executive.
Baseline data, data on hemophilia and joint history will be obtained by using questionnaires and patient history.

Contactpersonen

Publiek

Erasmus MC
S.C.M. Stoof
Rotterdam
The Netherlands

Wetenschappelijk

Erasmus MC
S.C.M. Stoof
Rotterdam
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

− Patients with mild, moderate or severe hemophilia A or B

− Age >12 years

− No clinical evidence of a recent joint or muscle bleed; no joint or muscle bleed at least 30 days prior to inclusion

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

− Inability to walk 20 meters without use of assistive devices

− Joint replacement in knee, ankle or hip

− Arthrodesis of foot and ankle joints

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2014
Aantal proefpersonen:	100

Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-02-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4439
NTR-old	NTR4561
Ander register	MEC : MEC-2014-086

Resultaten

Samenvatting resultaten
N/A