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

No registrations found.

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

Summary

ID

NL-OMON22693

Source
NTR

Brief title
MOVE study

Health condition

hemophilia, gait pattern, arthropathy, gaitSMART, footwear

hemofilie, looppatroon, artropathie, gaitSMART, schoeisel

Sponsors and support

Primary sponsor: Erasmus University Medical Center, Sophia Children's Hospital, Rotterdam, the Netherlands
Source(s) of monetary or material Support: Pfizer

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

− Number (%) of patients with Hemophilia Joint Health Score=0 and a disturbed gait pattern as defined above.

− Differences in outcome parameters of the gait analysis barefoot, on standardized walking shoes and on own shoes.

Study description

Background summary

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.

Study objective

- 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)

Study design

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

Intervention

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.

Contacts

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

Eligibility criteria

Inclusion criteria

− 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

Exclusion criteria

− Inability to walk 20 meters without use of assistive devices

− Joint replacement in knee, ankle or hip

− Arthrodesis of foot and ankle joints

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2014
Enrollment:	100
Type:	Actual

Ethics review

Positive opinion

Date:	13-02-2014
Application type:	First submission

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	ID
NTR-new	NL4439
NTR-old	NTR4561
Other	MEC : MEC-2014-086

Study results

Summary results
N/A