Equinovarus foot function after stroke

No registrations found.

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

Summary

ID

NL-OMON20535

Source
NTR

Brief title
CVA-foot

Health condition

equinovarus foot
stroke
foot and ankle kinematics
soft tissue surgery

Sponsors and support

Primary sponsor: Ir. Miriam Luizink (director)
Roessingh Research and Development
Roessinghsbleekweg 33 b
7522 AH Enschede
The Netherlands
Source(s) of monetary or material Support: Roessingh Research and Development
Roessinghsbleekweg 33 b
7522 AH Enschede
The Netherlands

Intervention

Outcome measures

Primary outcome

Lower extremity body motion (kinematics) during gait

Secondary outcome

FUNCTION

• Forceplate: The body loading (kinetics) during gait .

• Motricity Index, lower extremity: rapid overall indication of limb impairment and a validated measure for strength of the lower extremity

• Ankle dorsiflexor muscle strength will be assessed by means of a hand-held dynamometer.

• The muscle activation patterns of the leg and foot muscles
v

WALKING ABILITY

• Timed Balance Test

• Timed Up and Go (TUG)

• L-test

• 10 meter walk test (10 m WT)

• 6 minute walk test (6 minWT) to assess walking endurance [Kosak 2005, Tyson 2009].

• Foot and Ankle Ability Measure (FAAM) to assess the ability and difficulty to walk and stand during various daily activities

• Barefoot mobility, 3 questions will be included to assess ability and difficulty to walk bare foot while getting in and out of the bed, walking to the toilet and personal care.

• Rate of perceived Exertion (RPE or Borg scale) is scored for the L-test barefoot and for the 6 min WT (wearing shoes)

• Functional Gait Assessment (FGA)

• Functional Ambulation Categories (FAC) to assess the level of physical support needed to walk safely and to assess where the participant can walk.

PARTICIPATION

• Three patient specific complaints (PSK's) are assessed and scored on a visual analogue scale (VAS) with each a maximum score of 100 points.

• Stroke Impact Scale (SIS) version 3.0 to assess impairments and quality of life .

• Nottingham Extended ADL to assess the ability to independently perform activities in daily life regarding mobility, kitchen activities, household and recreation.

• Falls Efficacy Scale International (short-FES-I)

Study description

Background summary

Rationale: Equinovarus is the most frequently seen foot deformity in the affected leg after stroke and compromises the patient's walking ability and participation in daily life. Surgical intervention is a promising therapy since it enables the patient to walk more independently, barefoot, without the need of an orthosis. However, the effects of the foot and ankle surgery on restoring foot and ankle kinematics and kinetics, walking ability and on quality of life are not or not extensively studied.

Objective: The aims of this study are to explore the effects of foot and ankle surgery on the equinovarus foot deformity of patients after stroke in terms of foot function, walking abilities and social participation.

Study design: This study has an exploratory design with two measurement sessions: one 2 months before and the other 6 months after foot and ankle surgery.

Study population: Twenty adult stroke survivors who are patients at the Roessingh Rehabilitation Centre, with chronic hemiplegia and walking disabilities due to an equinovarus foot deformity will participate. These stroke patients are selected clinically to undergo equinovarus surgery and are subsequently asked to participate in this study by their rehabilitation physician.

Intervention: The intervention consists of standard techniques applied in soft-tissue surgery of equinovarus foot deformities.

Main study parameters/endpoints: The main study parameters includes the effect of surgery on restoring foot and ankle kinematics (motion). Furthermore, the effects of surgery on walking ability such as walking speed and endurance and fall risk, as well as daily participation measures is assessed.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks for the subjects are limited, since the tasks represent functional and familiar movements and are performed within a safe environment. When fatigue occurs, the subjects are able to rest till recovered. Furthermore, a therapist may walk along with the subject in cases necessary or requested. In addition, most measurements used in this study are non-invasive and involve no risks to the subjects in any way. The only invasive measure is performed according to standard clinical procedures.

Participation of a subject in this experiment has no direct benefit for him/her, other than expanding knowledge about the effects of foot and ankle equinovarus surgery on restoring foot and ankle function and walking ability.

Study objective

Exploratory study to develop hypotheses

Study design

Two measurement points:

1. One-two months before foot and ankle equinovarus soft tissue surgery

2. 6 months after surgery

Intervention

The measurements will take place befor and after standard soft-tissue surgery

Contacts

Public
Postbus 310
Rosemary Dubbeldam
Enschede 7500 AH
The Netherlands
+31 (0)53 4875700
Scientific
Postbus 310
Rosemary Dubbeldam
Enschede 7500 AH
The Netherlands
+31 (0)53 4875700

Eligibility criteria

Inclusion criteria

1. Unilateral ischaemic or haemorrhagic hemiparetic stroke

2. Time since stroke > 6 months

3. Age 18 years or older

4. Walking disabilities and/or fall incidents and/or pressure sores on the foot and/or unable to walk bare foot due to structural or dynamic equinovarus foot deformity, including

a. problems with stability in stance

b. problems with foot clearance during swing

c. problems with foot prepositioning in early stance

5. Subject is able to participate in an 1.5 hour session, including several stand and walking activities (walking aids allowed) with breaks in-between

Exclusion criteria

1. Complicating medical history such as cardiac, pulmonary, neurological or orthopaedic disorders that could affect performance of the included measurements

2. Neurolysis (fenol/alcohol) < 8 months

3. Motorpoint blockage (btx) < 5 months

4. Suffering from severe neglect

5. Severe comprehensive aphasia

6. Severe cognitive disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	20-10-2016
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-07-2016
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	NL5809
NTR-old	NTR5964

Register	ID
Other	CCMO dossier number : ABR 58628

Study results

Summary results
n.a.