Effect of surgery on foot function in the management of equinovarus foot deformity following stroke

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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. Furthermore, the relationships...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON55426

Source
ToetsingOnline

Brief title
Equinovarus foot function after stroke

Condition

- Central nervous system vascular disorders

Synonym
cerebral vascular accident (CVA), stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: Innovatiecentrum Revalidatietechnologie;Ministerie VWS

Intervention

Keyword: Equinovarus foot deformity, Foot and ankle kinematics, Soft tissue surgery, Stroke

Outcome measures

Primary outcome

The main study parameters includes the effect of surgery on restoring foot and ankle kinematics (motion).

Secondary outcome

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.

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.

Study objective

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. Furthermore, the relationships between pre-surgical factors (function) and improvements in activity and participation will be studied.

Study design

Study design: This study has an exploratory design with two measurement sessions of one day each: one in the period before and the other 6 months after

foot and ankle surgery. If this is impossible for the participant, only the questionnaires can be filled in at home. The intervention consists of standard techniques applied in soft-tissue surgery of equinovarus foot deformities.

Study burden and risks

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.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 selected for surgical correction of equinovarus foot only (so no intervention to structures around knee that may influence gait)
6. 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 severely 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 invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-03-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	02-12-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	22-10-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-03-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-08-2021
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
Other	Nederlands trial register
CCMO	NL58628.044.16