Towards evidence-based surgical interventions in chronic stroke patients with pes equinovarus deformity

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The primary objective of this study is to evaluate the effect of surgical correction of pes equinovarus deformity compared to conservative treatment on personalized goal attainment. In addition, we will evaluate the effect of surgical correction of...

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

Summary

ID

NL-OMON20001

Source
NTR

Brief title
TARGET

Condition

- Central nervous system vascular disorders

Health condition

Stroke patients with pes equinovarus deformity

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: N/A

Intervention

- Surigical procedure

Explanation

Outcome measures

Primary outcome

Concerning personalized goal attainment: - Canadian Occupational Performance Measure (COPM) Concerning gait capacity: - Timed-Up-And-Go test Concerning daily life gait performance: - Quantity: activity duration

Secondary outcome

Concerning gait capacity: - Self-selected gait speed - Cadence - Step length - Step-length symmetry - Single-support time - Single-support time symmetry - Hip-knee-ankle-foot kinematics - Peak ankle moment - Peak ankle power - Plantar pressure patterns - Mini-BESTest - Margin of Stability - Stepping error precision stepping Concerning daily life gait performance: - Quality: gait velocity - Quality: step length - Quality: cadence Other: - Surgical complications

Study description

Background summary

Acquired brain injury is the leading cause of disability in the western world. In patients with acquired brain injury, balance and gait impairments due to pes equinovarus deformity are common and disabling. It predisposes to hindfoot instability, reduced gait speed and distance, dependence on walking aids, pain while walking, and ultimately reduced functional mobility.

In the chronic phase after acquired brain injury, training does not improve pes equinovarus. Therefore, the emphasis of management should be on medical-technical interventions. Both nationally and internationally, however, there is relative underuse of surgical treatment options, although in our clinical experience this often has the best outcome.

In 2019, our group published a pilot observational study reporting a 30% increase in gait speed after surgical interventions. These preliminary results suggest surgical interventions for pes equinovarus deformity improve gait capacity in chronic stroke patients, and that the degree of improvement is of great clinical relevance. Further substantiation using clinical

trials and a better understanding of the underlying mechanism is now needed.

Study objective

The primary objective of this study is to evaluate the effect of surgical correction of pes equinovarus deformity compared to conservative treatment on personalized goal attainment. In addition, we will evaluate the effect of surgical correction of pes equinovarus deformity on gait capacity and daily life gait performance.

Study design

Observational intervention study with repeated-measures. Additionally, a database that contains the measurements of people who have visited the Sint Maartenskliniek for routine clinical care will be analyzed in this study.

Intervention

Surgical correction of pes equinovarus deformity

Study burden and risks

There are no serious risks associated with participation in this study. Many measurements that will be performed in this study are already part of routine clinical care within the LEC. The additional measurements do not lead to increased risk, since appropriate safety measures will be taken such as wearing a safety harness to prevent falling during the regular walking task and while performing precision stepping and small perturbations in the Gait Real-time Analysis Interactive Lab (GRAIL).

The subjects will visit the clinic three times for performing measurements. Two visits are already part of routine clinical care. It is estimated that the measurements will take 5 hours in total in addition to the regular clinical treatment trajectory.

Contacts

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Eligibility criteria

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

Inclusion criteria

- > 6 Months post onset - 18 Years or older

Exclusion criteria

- Suffers from any other disorder that seriously affects gait capacity - Underwent a surgical intervention of the ankle/foot in the past two years

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2021
Enrollment:	22
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO Date:	11-08-2021
Application type:	First submission
Review commission:	METC Oost-Nederland
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Study registrations

Followed up by the following (possibly more current) registration

ID: 54441
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9696
CCMO	NL77992.091.21
OMON	NL-OMON54441

Study results