Towards evidence-based surgical interventions in patients with acquired brain injury and pes equinovarus deformity

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

Summary

ID

NL-OMON54441

Source
ToetsingOnline

Brief title
Surgical correction of pes equinvarus deformity

Condition

- Central nervous system vascular disorders

Synonym
Acquired brain injury (ABI)

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Sint Maartenskliniek

Intervention

Keyword: Acquired brain injury, Ankle-foot, Pes equinovarus, Surgical intervention

Outcome measures

Primary outcome

Primary outcome will be the attainment of predefined personal goals as measured

with the Canadian Occupational Performance Measure (COPM).

Secondary outcome

The secundary outcome measures of this study are:

- 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

- Daily life: gait velocity

- Daily life: step length

- Daily life: cadence

- 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 the quantity and quality of daily life gait performance.

Study design

Observational intervention 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

All patients will receive a personalized surgical intervention to obtain optimal stability of the foot in the frontal plane. The personalized surgical intervention is part of routine clinical care at the Sint Maartenskliniek. It

consists of a fusion of one or more tarsal joints in combination with other interventions such as the fixation of the interphalangeal toe joints, Achilles tendon lengthening, or other tendon releases/ lengthenings/ transfers.

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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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Acquired brain injury patients with pes equinovarus deformity
- > 6 months post onset
- Patients have to be 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 type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-09-2021
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO

Date:	11-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-02-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-04-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-08-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-02-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20001
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL77992.091.21