A lower-limb powered exoskeleton for stroke patients: a feasibility study

Published: 18-08-2021
Last updated: 05-04-2024

Determine if the ABLE-S exoskeleton can provide subject-specific assistance (in terms of type, level and timing of the assistance) to increase forward propulsion, foot clearance and/or knee stability, in hemiplegic stroke patients.

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

Summary

ID

NL-OMON51195

Source
ToetsingOnline

Brief title
ABLE After Stroke

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: DIH Hero;Europese subsidie

Intervention

Keyword: Exoskeleton, Lower limb, Stroke

Outcome measures

Primary outcome

The main outcome parameters are joint angle of ankle and knee, to assess the ankle and knee movement. In other words, the dorsiflexion and plantarflexion of the ankle and the flexion and extension of the knee.

Secondary outcome

Secondary study parameters related to the gait analysis are spatiotemporal and kinematic parameters, ground reaction force and muscle activity. Next to these gait related parameters, the BORG rating scale will be administerd after each condition and questionnaires to evaluate the usability and experience of the patient.

Study description

Background summary

Stroke is one of the leading causes of disability of adults in the European Union. Around 80% of stroke survivors experience deficits in motor control, which results in gait and balance problems. The extent and amount of deficits differ per individual Frequently occurring motor impairments are spasticity of the plantar flexor muscles, muscle weakness of dorsiflexors and/or knee instability. An ankle foot orthoses (AFO) is frequently used to ensure stable and safe walking. However, a passive AFO does not support push-off, which is frequently injured in post-stroke patients. In the current study a powered lower extremity exoskeleton (ABLE-S) will be assessed. It should provide assistance during the push-off to increase forward propulsion and foot clearance and improve knee stability.

Study objective

Determine if the ABLE-S exoskeleton can provide subject-specific assistance (in terms of type, level and timing of the assistance) to increase forward propulsion, foot clearance and/or knee stability, in hemiplegic stroke patients.

Study design

The current study is a cross-sectional observational study.

Study burden and risks

The current study consists of two visits to the lab of Roessingh Research and Development. During these visits several tests will be performed with ABLE-S and Vicon markers. There is no direct advantage for the participants and there are no negative effects of the planned measurements because the study load is low and there is enough room for rest between the different trials. The ABLE-S exoskeleton is not CE-certified and the main risk is a fall risk, this will be handled carefully by close supervision and familiarization with ZeroG.

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

* Age above 18 years
* Left unilateral ischemic or haemorrhagic chronic (> 6 months) stroke
* Hemiparetic right leg
* Problems with stability in stance, insufficient push-off, problems with foot clearance during swing and/or problems with foot prepositioning in early stance.
* Functional Ambulation Categories (FAC) score * 3, participants are able to walk without manual assistance on a flat surface.
* Able to walk without walking aids (such as crutch, four-wheeled walker)
* Able to read and understand questionnaires and able to understand and execute commands, both in Dutch.

Exclusion criteria

* High levels of spasticity of muscle tone (resistance to passive movement), as represented by modified Ashworth scale scores of 3 or higher
* Premorbid disability of lower extremity
* Progressive neurological diseases like, dementia or Parkinson
* Skin lesions or severely impaired sensation at the hemiparetic leg
* Contraindication for mobilization, like lower limb fracture
* Pregnancy

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):	12-10-2021
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	ALBE-S
Registration:	No

Ethics review

Approved WMO Date:	18-08-2021
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL77959.000.21
Other	NL9428