Clincial feasibility of ROBERT-SAS in severely affected stroke patients

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The primary objective of the current study is to assess the feasibility of ROBERT® -SAS training in clinical setting, in acute stroke patients, including patient and therapist perspectives

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

Summary

ID

NL-OMON51596

Source
ToetsingOnline

Brief title
Clincial feasibility ROBERT-SAS

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: EUREKA;europese subsidie

Intervention

Keyword: electrical stimulation (ES), Robotic, Stroke

Outcome measures

Primary outcome

The main outcome parameter is the SUS score from both the patients and the therapists.

Secondary outcome

In addition to the primary outcome, the surface EMG and resulting force will be noted with the ROBERT® -SAS system. Furthermore, the selected mode of ROBERT® -support, SAS parameter settings (including amplitude, frequency and pulse width of ES) and the treatment settings on the screen will be stored. The trajectory completion rate will be determined between the different AAN stages. Exercises specific settings such as repetitions and resistances settings, are collected. Clinical measurements like the Fugl-Meyer assessment, Motricity index and forces measured with the MRC test will be recorded over time. Furthermore, information about the clinical applicability will be gathered. This information contains information like, the settings that will be used, the movement that are trained, the time the training and set-up takes (separately timed) and lastly the training duration (in case of continuing training beyond 3 weeks) and its reasons as reported by therapists (e.g. which aspects were considered in deciding to prolong the training beyond three weeks).

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, resulting in problems with keeping balance and walking, for instance. The extent and amount of deficits differ per individual. Interventions to train the lower extremity almost always consist of walking exercises. However, patients in the acute phase or with severely affected lower extremity function are often unable to walk or to walk independently. Therefore, the combination of a robot (ROBERT®) and functional electrical stimulation (ES) is being developed to provide a training tool for early rehabilitation. In the current study a combination of robot and ES will be evaluated in clinical setting.

Study objective

The primary objective of the current study is to assess the feasibility of ROBERT® -SAS training in clinical setting, in acute stroke patients, including patient and therapist perspectives

Study design

The current study is an observational study.

Study burden and risks

The current study consists of several measurement sessions in Roessingh rehabilitation centre, during the normal rehabilitation time. The robot, ROBERT® is CE-certified. However, the combination ROBERT® -SAS, combining both ES and robot support, is not, although previous tests have shown this approach is possible and tolerable by healthy persons and stroke patients. The risks are regarded as minimal because it is without invasive procedures, with room for rest in between trial sets as required by the participant, and application of individual stimulation profiles to not exceed tolerance levels or inflict pain during electrostimulation.

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

• Sub(acute) stroke (< 6 months post-stroke)
• Above 18 years
• Able to provide informed consent
• An ischemic or haemorrhagic stroke
• Hemiparetic lower extremity

Exclusion criteria

• Premorbid disability of lower extremity
• Severe cognitive impairment, unable to follow simple instructions and unable to understand Dutch.
• Skin lesions at the hemiparetic leg
• Progressive neurological diseases (i.e. Parkinson, dementia, etc.)
• Contraindication for mobilization like lower limb fracture
• Use of pacemaker
• Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2022
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	ROBERT-SAS
Registration:	No

Ethics review

Approved WMO

Date:	22-06-2022
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	NL80574.000.22