Feasibility of ROBERT-SAS in severely affected stroke patient

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22211

Source
NTR

Brief title
ROBERT-SAS

Health condition

Stroke

Sponsors and support

Primary sponsor: Roessingh Research and Development
Source(s) of monetary or material Support: EUREKA/European union

Intervention

Outcome measures

Primary outcome

The main outcome parameter is the success rate of intention detection, expressed as the % of times the electrostimulation threshold is reached.

Secondary outcome

In addition to the primary outcome, segment position, force, trajectory completion rate and muscle activity will be measured during the measurements. From the position data the joint angles will be derived, the force is measured with a built in force sensor in ROBERT and the muscle activity with sEMG electrodes.

Study description

Background summary

Rationale: 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 prototype will be evaluated in a lab-based setting, in order to provide information for the future development of the ROBERT-SAS combination.
Objective: Determine the detection success rate of movement intention detection based on muscle activity during leg press and ankle dorsiflexion in stroke patients. In addition, the joint angles, forces, muscle activity and user experience will be assessed.
Study design: The current study is a cross-sectional observational study.
Study population: Twenty participants with a (sub-)acute stroke and moderately-severely affected lower extremity function will be included in the current study. All participants should have a unilateral stroke, score between 0-25 on the motricity index per segment (knee or ankle) and an age above 18 years.
Main study parameters/endpoints: The main outcome parameter the success rate of intention detection, expressed as the % of times the electrostimulation is triggered. In addition, trajectory completion rate, hip, knee and ankle joint angles, net force and muscle activity are assessed to compare between different intention detection methods and against movement without support from ROBERT-SAS.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The current study consists of one visit to the lab of Roessingh Research and Development. 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. There is no direct advantage for the participants, but the risks are regarded as minimal because he study load is relatively low, 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.

Study objective

It is expected that the Maximum voluntary contraction (MVC) method is preferered over the rest EMG method. Because, stroke patients expierence a unvoluntary contractions, spasticity etc. which influences the rest EMG.

Study design

Only one measurements where all the primary and secondary outcome measurements will be measured/obtained. In case of fatigue the measurements will be reduced to for example one movement.

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

• Sub(acute) stroke (< 6 months post-stroke)
• Above 18 years
• Able to provide informed consent
• Unilateral ischemic or haemorrhagic stroke
• Hemiparetic lower extremity
• Motricity index (MI) between 0-25 (for both knee and ankle). That means varying between no palpable contraction (muscle activity recordings are more sensitive than palpation) and full movement, but weaker than the other leg.

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
• Contraindication for mobilization like lower limb fracture
• Use of pacemaker
• Pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-07-2021
Enrollment:	5
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
not applicable

Ethics review

Positive opinion

Date:	29-07-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50980
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9636
CCMO	NL76919.091.21
OMON	NL-OMON50980

Study results

Summary results
none