Feasibility of ROBERT-SAS in severely impaired stroke patients

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In the current study a prototype will be evaluated in a lab-based setting. This in order to provide information for the development of the ROBERT-SAS combination.

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

Summary

ID

NL-OMON50980

Source
ToetsingOnline

Brief title
Feasibility of ROBERT-SAS

Condition

- Central nervous system vascular disorders

Synonym
Cebrovascular accident, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: EUREKA;subsidie EU

Intervention

Keyword: Functional electrical stimulation (FES), Robotic, Stroke

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcome values are: position, force, FES amplitude, trajectory completion rate (per stage 1-3), timing and velocity parameters and muscle activity. From the position data the joint angles will be derived, the force is measured with a build in force sensor and the muscle activity with sEMG electrodes.

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 (FES) is developed to provide a rehabilitation at bedside.

Study objective

In the current study a prototype will be evaluated in a lab-based setting. This in order to provide information for the development of the ROBERT-SAS combination.

Study design

The current study is a cross-sectional observational study.

Study burden and risks

The current study consists of at least one visit and maximal five visits to the lab of Roessingh Research and Development. The robot, ROBERT is CE-certified. However, the combination ROBERT-SAS, combining both FES 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.

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
• Above 18 years
• Able to provide informed consent
• Unilateral ischemic or haemorrhagic stroke
• Hemiparetic lower extremity

Exclusion criteria

• Premorbid disability of lower extremity
• Progressive neurological diseases like, dementia or Parkinson
• 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
• Pacemaker
• Pregnancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-08-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	19-04-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-11-2021
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: 22211
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL76919.091.21
OMON	NL-OMON22211