Feasibility of ROBERT-SAS in severely affected stroke patient

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22211

Bron
NTR

Verkorte titel
ROBERT-SAS

Aandoening

Stroke

Ondersteuning

Primaire sponsor: Roessingh Research and Development
Overige ondersteuning: EUREKA/European union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Roessingh Research and Development
Cindy Rikhof

0880875777

Wetenschappelijk

Roessingh Research and Development
Cindy Rikhof

0880875777

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-07-2021
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
not applicable

Ethische beoordeling

Positief advies

Datum:	29-07-2021

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50980
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
none