Understanding motor control in the lower extremity in severely impaired stroke patients

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It is expected that the affected lower extremity has lower motor control than the unaffected side and in severely affected stroke patient, the motor control is lower compared to less affected stroke patients.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22674

Bron
Nationaal Trial Register

Verkorte titel
Motor control in stroke patients

Aandoening

Stroke

Ondersteuning

Primaire sponsor: Roessingh Research and Development
Overige ondersteuning: EUREKA subsidy European Union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main outcome parameter in the current study is muscle activity of the nine lower limb muscles measured with (HD-)sEMG (High Density surface electromyography). The muscle activity will be measured during maximal voluntary contractions (MVC) measurements in both single joint and a multi-joint tasks, for both the affected and non-affected leg. Different parameters will be used to evaluate the muscle activity in severely affected stroke patients. The parameters are based on frequency, amplitude and timing. These parameters will be further elaborated in the statistical analysis. Muscles that will be measured with sEMG during movement of the lower extremity are:
• Quadriceps femoris (Rectus femoris, vastus lateralis)
• Gluteus maximus
• Hamstring (biceps femoris, semitendinosus)
• Tibialis anterior
• Peroneus
• Triceps surae (gastrocnemius medialis and soleus)
From these muscles the vastus lateralis and tibialis anterior will be measured with HD- sEMG. The HD-sEMG set up will allow for inference of bipolar sEMG to match the bipolar sEMG data acquired from the other muscles listed above. In other words, the vastus lateralis and tibialis anterior muscle activity data can be analysed using the 'normal' bipolar sEMG signals, similar as for the remaining muscles, as well as the spatial bipolar HD-sEMG signals.

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. In addition, there is a limited amount of knowledge about the muscle activity in these patients. Therefore, the current study proposes to investigate the motor control in this group. This in order to provide information for follow-up research into robot assisted rehabilitation (ROBERT) combined with functional electrical stimulation (FES) targeted at severely impaired stroke patients.
Objective: Determine the differences in timing, frequency and magnitude of the muscle activity signals during static conditions in stroke patients with severely affected lower extremity function, between the affected and non-affected leg.
Study design: The current study is a cross-sectional observational study.
Study population: Ten participants with a chronic stroke and severely affected lower extremity function will be included in the current study. All participants should have a unilateral stroke, score ≥ 18 and ≤ 75 on the motricity index and an age above 18 years.
Main study parameters/endpoints: The main outcome parameter in the current study is muscle activity of the different muscles during performance of specified static tasks. Different parameters in terms of frequency, amplitude and timing will be subtracted from the muscle

activity data.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The current study consist of one visit to the lab of Roessingh Research and Development. The muscle activity will be measured with surface electrodes and maximal force with a prefixed framework. All measuring instruments are CE-certified and are used following the user guides and the intended use. There is no direct advantage for the participants and there are no negative effects of the planned measurements because the study load is relatively low, with room for rest in between trial sets as required by the participant and all forces exerted by the participants will be within their individual capability.

Doel van het onderzoek

It is expected that the affected lower extremity has lower motor control than the unaffected side and in severely affected stroke patient, the motor control is lower compared to less affected stroke patients.

Onderzoeksopzet

One time point. At this time point the muscle acitivity will be measured with (HD-)sEMG, the force with force sensors and some general characteristics will be noted, like age, gender and clinical tests. The clinical tests entail the motricity index, fugl-meyer and functional ambulation catagories. The muscle activity and force will be measured in single joint and multi-joint setting. Both the primary and secondary outcomes will be gatherd during this one time point, which will take about 2.5 hours in total.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Chronic stroke
• Above 18 years
• Able to provide informed consent
• Unilateral ischemic or haemorrhagic stroke
• Hemiparetic lower extremity
• Motricity index ≥18 and ≤75. There is at least palpable contraction and maximal full movement, but weaker than the other side.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Premorbid disability of lower extremity
• Progressive neurological diseases like, dementia or Parkinson
• Severe cognitive impairment, unable to follow simple instructions.
• Skin lesions at the hemiparetic leg
• Contraindication for mobilization like lower limb fracture

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 nog niet gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	20

Type: Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9157
Ander register	CMO Arnhem Nijmegen issued it as n-WMO : 2020-7205/NL75703.091.20

Resultaten