Modelling human neuromuscular responses to electro-mechanical stimuli after neurological injuries

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Observational invasive

Summary

ID

NL-OMON49185

Source
ToetsingOnline

Brief title
Modelling neuromuscular responses to electro-mechanical stimuli

Condition

- Neuromuscular disorders

Synonym
incomplete spinal cord injury, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: European Research Council Starting Grant

Intervention

Keyword: dynamometry, high-density electromyography, musculoskeletal modelling, spinal cord electrical stimulation

Outcome measures

Primary outcome

The primary outcome of this study are models capable of estimating the following neuro-mechanical parameters: joint kinematics, human-machine interaction forces, amplitude of mechanically-induced reflexes, and motor neuron parameters (e.g. discharge rate, inter-spike intervals and coherence between spike trains).

Secondary outcome

All the subjects will be asked to fill out a questionnaire that assesses physical and physiological factors that may be of relevance for the analysis.

These characteristics are the following:

• Sex

• Age (years)

• Weight (kg)

• Height (m)

• Leg length (m)

• Use of sedatives and analgesics

• Other neurological disorders than stroke/SCI

• Chronic pain

• History of depression

• History of diagnosed cognitive deficit

Study description

Background summary

Human movement emerges from the interplay between the nervous and musculoskeletal systems. Despite knowledge of the mechanisms at the individual systems there are major gaps in the understanding of their interplay. In this study, both healthy and neurologically impaired populations are studied in highly controlled and safe experiments. The data collected from these experiments are used as a basis for creating detailed subject-specific numerical models of the composite neuromuscular system for ankle exoskeleton control and to validate them on healthy, stroke and spinal cord injury participants. These models might shed light on how human movement is modulated and how it is affected by neurological conditions. This knowledge can be used to design rehabilitation strategies highly personalized to the patient.to optimize recovery and thus improve their quality of life.

Study objective

The main objective of this study is to create and validate subject-specific models of the human neuromuscular system capable of estimating neuro-mechanical activity in vivo in healthy, post-stroke and SCI individuals. In addition, we want to prove that these models can predict how neuro-mechanical activity is altered by external devices including robotic dynamometers and ankle exoskeletons both in healthy, post-stroke and SCI individuals.

Study design

This is a one-site observational study consisting of three phases.

Study burden and risks

The study does not create direct benefits for the subjects, as the protocol just adds observational experiments on top of regular clinical care. The burden is minimal and the risks negligible, as the protocol consists of standard tests with a duration of less than three hours. In total, subjects will participate in three phases. Similar tests have already been executed/approved multiple times by the METC.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
• age between 16 and 85,
• legal capacity to give the consent at his/her own will;
for the stroke individuals:
• hemiparesis of the lower limb at chronic stage (> 3 months);
• impaired plantar flexion during walking
• MRC Grade 3 and above for the calf
• FAC score of 3 and above
• Ability to walk at least 6 minutes at their self-selected walking speed.
for the SCI individuals:
• chronic stage: time since SCI > 12 months,
• clear walking impairment but able to walk independently (without support), i.e. Walking Index for Spinal Cord Injury (WISCI) > 1 and spinal cord independence measure (SCIM) > 30,
• Motor incomplete spinal cord injury (ASIA impairment scale: C or D),
• Injury situated superior to the T9 vertebra.

• Ability to walk at least 6 minutes at their walking speed.

Exclusion criteria

Individuals fulfilling one of the following criteria will be excluded: Motor complete spinal cord injury (ASIA impairment scale: A or B),
• neuromuscular disease,
• pregnancy,
• addictive or previous addictive behaviour defined as the abuse of cannabis, opioids or other drugs,
• carrier of infectious diseases,
• degenerative mental impairment, e.g. dementia,
• inability to cooperate, e.g. due to cognitive deficits (in understanding instructions) or a level of motor impairment that does not permit execution of the intended tasks,
• subjects suffering from known cardiac conditions (e.g., pacemakers, arrhythmias, and cardiac conduction disturbances) or peripheral neuropathy.
• skin sensitivity or allergies as these are typical contraindications for the application of surface EMG electrodes via adhesive elements and conductive gels.
• Participating in an ongoing study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-07-2021
Enrollment:	75
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	16-09-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-05-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-12-2024
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

No registrations found.

In other registers

Register	ID
CCMO	NL73230.091.20