Robot-assisted gait training and assessment for neurological patients

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Primary objective: Determine for different control algorithms and robotic modules whether the algorithm and/or robotic module is effective in providing the patient with the required support and measure bringing about the desired changes in the...

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

Summary

ID

NL-OMON47656

Source
ToetsingOnline

Brief title
Robot-assisted gait training and assessment

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident / spinal cord injury, myelopathy, Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Robot-assisted rehabilitation, Spinal cord injury, Stroke, Walking pattern

Outcome measures

Primary outcome

This protocol describes a framework, according to which a set of studies and experiments can be designed that each might have slightly different main endpoints. The feasibility of a control algorithm and robotic module will might be assessed based on its ability to provide the patient with the required support in a safe and comfortable way, its ability to bring about the desired changes in walking pattern in healthy subjects and patients, and its ability to encourage patients in self-generating muscle activity and its ability to reduce metabolic cost in healthy subjects and patients.

Secondary outcome

The measured muscle activity will be used to determine whether the control algorithm encourages patients in self generating muscle activity. The responses in the joint movements to the robotically applied forces will be used to derive the subject specific impairments. The measured metabolic rate will be used to determine the effect of new control algorithms on the energy cost.

Study description

Background summary

Task-specific and intensive training of repetitive active movements results in the largest functional improvements in the rehabilitation of stroke patients and spinal cord injury patients. Providing this kind of therapy for gait training puts a high physical burden on therapists. For instance, in gait

training on a treadmill with partial bodyweight usually 2 therapists are needed to assist the patient in walking. In the past years, a new robot device, LOPES II or III, has been developed which can provide neurological patients with the necessary support in gait training. In LOPES II or III, the amount of support during walking can be adjusted, varying from high (robot-in-charge mode) to zero (patient-in-charge mode). The challenge is to apply as much support as the patient needs to perform the selected exercise. The support should allow the patient to walk and still encourage him/her to provide an active contribution. Different algorithms have been proposed but they are not yet tested for their feasibility in severely affected neurological patients.
Besides, different ankle modules have been developed for the LOPES III. One ankle module can be used to assist plantarflexion and dorsiflexion actively, however, other movements (inversion/eversion, endorotation/exorotation) might be restricted. With another ankle module, it is not possible to actuate the ankle, however, the subject can move more freely in different degrees of freedom (inversion/eversion, endorotation/exorotation, plantarflexion/dorsiflexion). LOPES II only has a non-actuated ankle module. In the future, additional robotic modules might be developed for the LOPES II or III. The effect of these different modules in healthy subjects and severly affected patients is unknown.
Additionally, to be able to tailor the support to the patient*s needs, the patient impairments need to be characterized. The response of patients to the robotic forces applied during walking can be used to derive a measure of the impairments that limit the walking ability

Study objective

Primary objective:
Determine for different control algorithms and robotic modules whether the algorithm and/or robotic module is effective in providing the patient with the required support and measure bringing about the desired changes in the walking pattern in healthy subjects and neurological patients.
Secondary objectives:
-Determine whether the different control algorithms and robotic modules result in changes of the self- generated activity of the neurological patients and healthy subjects.
-To determine whether different control algorithms and robotic modules result in changes of metabolic parameters in neurological patients and healthy subjects.
-Quantify the impairments that limit walking in neurological patients using LOPES II or III.
-Compare different control algorithms and robotic modules and determine which algorithms and modules might be most effective in providing the required support.

Study design

This protocol describes a framework according to which a set of studies and experiments can be designed. The different studies are designed as observational studies.

Study burden and risks

Subjects will participate in at least one session and maximally in 5 sessions. In the first session the subject will be asked to walk with LOPES II or III maximally 4 trials of maximal 7 minutes. The trials differ in the used algorithm to control LOPES II or III, the used robotic modules and/or the magnitude of the provided support. Depending on the patient*s physical condition and the physical effort in the first session, the amount of trials will be slowly upgraded to maximal 10 trials of maximal 7 minutes in subsequent sessions. Between the trials subjects will receive time to rest. The LOPES II and III device was extensively tested for safety. During all test the implemented safety measures will assure that the exerted torques and the performed movements are within safe limits.

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

In general the inclusion criteria for healthy subjects and SCI/stroke subjects are:
-age > 18 years
- a stable medical condition
- a physical condition which allows for 3 minutes of supported walking
- have sufficient cognitive abilities (Mini-Mental State Examination * 22) ;Specifically inclusion criteria for spinal cord injury patients are:
- a first ever SCI
- time since injury > 6 months
- complete or incomplete lesion (AIS A,B, C or D)
- injury to the spinal cord from below C6, on at least one side of the body
- able to sit unsupported (to sit upright without using the hands or an external support)
;Stroke patients are explicitly included in the study if they:
- are diagnosed with a hemiparesis as the result of a stroke
- have had the stroke > 6 months ago
- score 1 to 4 on the functional ambulation classification
- have sufficient communication abilities (Utrechtse Communicatie Onderzoek * 3)

Exclusion criteria

Healthy subjects, spinal cord injury patients and stroke patients are excluded if they:
- have current orthopaedic problems
- other neurological diseases
- have a history of cardiac conditions that interfere with physical load
- had no independent ambulation prior to SCI or stroke,
- have contraindication for lower extremity weight bearing (chronic joint pain, fracture)
- inappropriate or unsafe fit of the robotic trainer due to the participant*s body size (bodyweight > 100 kg) and/ or joint contractures.
- have spin-stabilizing devices for whom their treating surgeon contraindicates gait
- have pressure sore stage 2 or higher

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-07-2017
Enrollment:	130
Type:	Actual

Medical products/devices used

Generic name:	LOPES II/III
Registration:	No

Ethics review

Approved WMO Date:	24-05-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-12-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	20-12-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL61422.044.17