The effects of body weight support, guidance, and gait speed on patterns of muscle activity in the Lokomat, in persons with post stroke hemiparesis and in healthy walkers

Published: 05-02-2014
Last updated: 15-05-2024

a. To establish the effects of (1) body weight support (2) treadmill speed, and (3) level of guidance/ movement support, on the neuromuscular control of the lower extremities in patients with post-stroke hemiparesis, and to determine possible...

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

Summary

ID

NL-OMON40378

Source
ToetsingOnline

Brief title
Patterning of muscle activity in the Lokomat in persons with stroke

Condition

- Central nervous system vascular disorders

Synonym
cerebrovascular accident (CVA); Stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Gait, Muscle activity, Robotics, Stroke

Outcome measures

Primary outcome

The amplitude of muscle activity in µvolts.

Secondary outcome

D.N.A.

Study description

Background summary

The Lokomat is a position-controlled exo-skeleton that can be used to train gait skills in stroke patients with impaired gait. During training in the Lokomat, the following parameters can be set: (1) speed of the treadmill (2) the level of body weight support (3) the level of movement support or *guidance*. For adequate use of these parameters, and for the development of treatment protocols for the Lokomat, it is important to understand how these training parameters affect the gait pattern of patients. In addition, it is important to know the extent to which, over different training sessions, patients react in a stereotyped fashion to the training parameters or whether they show a large session-to-session variability in their gait patterns in the Lokomat. A logical strategy to assess these gait patterns is to record the muscle activity that is responsible for the production of these patterns.

Study objective

a. To establish the effects of (1) body weight support (2) treadmill speed, and (3) level of guidance/ movement support, on the neuromuscular control of the lower extremities in patients with post-stroke hemiparesis, and to determine possible differences in these effects (1) between patients and healthy, age-matched controls, and (2) between the impaired and unimpaired leg in patients.

b. To compare the patterns of muscle activity displayed in in the exo-skeleton of the Lokomat, and during walking on the treadmill outside the exo-skeleton, and to determine whether the effects of the exo-skelton differ between hemiparetic stroke patients and their healthy peers.

c. To determine the between session variability in muscle activity in the Lokomat, and to establish possible differences in between session variability between hemiparetic stroke patients and their healthy peers.

Study design

Participants will be required to walk in the Lokomat while activity is recorded by means of electromyography (EMG) from the following 5 muscles: (1) Gastrocnemius medialis (2) Tibialis anterior (3) Vastus medialis (4) Biceps femoris and (5) Gluteus medius. In patients, these muscles will be recorded in both legs, whereas in healthy subjects only the preferred leg will be assessed.

During each individual trial, a unique combination of treadmill speed (2 levels: 1.0, and 2.0 km/h), body weight support (0% and 50% of the participant*s body weight), and guidance (50%, and 100%) will be presented. In total, participants will perform (2x2x2=) 8 trials in the Lokomat. In addition, all combination of body weight support and treadmill speed will also be presented outside the exo-skeleton on the treadmill (4 trials). So, a total of 12 trails will be performed.

To establish the inter-session variability and to compare this between healthy and hemiplegic walkers, the trails in the Lokomat exo-skeleton will be repeated for each participant between 7 and 14 days after the first test session.

Intervention

A total of 10 (2 for each muscle that will be recorded) self-adhesive electrodes will be placed on the skin of participants. In patients, activity from both legs will be recorded.

Study burden and risks

Walking in the exoskeleton may be somewhat fatiguing to some people, when extremely low treadmill speeds (< 2km/h) and high levels of body weight support (> 30% of body weight) are used. Because participants wear a harness, and the treadmill Is equipped with hand rests, participants will not be able to fall.
In case of unexpected calamities, the experimenter as well as the participant can press a *emergency-stop*, which will halt the treadmill and the exo-skeleton immediately. In addition, the Lokomat has a built-in safety mechanism which will halt the apparatus immediately in case unexpected movements are detected. If walking in the Lokomat becomes uncomfortable for

some reason (e.g. skin irritation, pain in muscles/tendons), the participant can indicate this and the experiment will be paused or aborted.

During testing of patients, his/her physiotherapist will present. The therapist is certified for making adjustments to and training with the Lokomat, and can provide extra instructions to the patient for easier progress of the test, or can relieve or take away discomfort when necessary.

The required gait activity of participants is similar to everyday walking. The participant is not likely to experience any burden from the electrodes of the EMG system. In the light of the relatively low burden and the small risks associated with this study, it seems justified to conduct this study because it may yield important information that can be used to develop training protocols for neurological patients.

Contacts

Public
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
Groningen 9713 AV
NL
Scientific
Universitair Medisch Centrum Groningen

Antonius Deusinglaan 1
Groningen 9713 AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1. First ever, unilateral stroke (infarction or hemorrhage)
2. At least 3 months post onset
3. Unilateral paresis of the leg
4. A Functional Ambulation Categories Score of 2 (Patient needs continuous or intermittent support of one person to help with balance and coordination**), 3 (*Patient requires verbal supervision or stand-by help from one person without physical contact*), or 4 ('*Person can walk independently on level ground, but requires help on stairs, slopes or uneven surfaces*).
5. Patient should be older than 18 years to be included

Exclusion criteria

1. Severely impaired cognitive functions (Mini Mental State Exam score <=25)
2. Severe speech, language or communication disorders (left to clinical judgment whether the patient is able to understand instructions and to provide informed consent; in case of doubt the Aachen Aphasia Test will be administered).
3. Insufficient working knowledge the Dutch language to understand instructions and provide informed consent (clinical judgment).
4. Severe visual problems (clinical judgment).
5. Severe neglect (clinical judgment through observation. In case of doubt, the Star Cancelation Test can be administered).
6. Co-morbidity that can affect the results of the study (e.g. pre-existent problems in leg function or a progressive neurological disorder).
7. Participation in other scientific studies.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-04-2014
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	05-02-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-05-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-10-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 28557
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL46137.042.13
OMON	NL-OMON28557