The effects of providing asymmetrical guidance during Lokomat guided gait on muscle activity in persons with post-stroke hemiparesis

Published: 31-10-2017
Last updated: 12-04-2024

Primary Objective: To establish the effect of asymmetrical guidance provided by the Lokomat exoskeleton on levels of muscle activity in persons with post stroke hemiparesis. Secondary Objective(s): (i) To establish if the abovementioned effects (see...

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

Summary

ID

NL-OMON44481

Source
ToetsingOnline

Brief title
The effect of asymmetrical guidance in the Lokomat

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

Research on bi-pedal pedaling has shown that movements of the ipsilateral leg give rise to structured activity of muscles in the contralateral, stationary leg. This shows that during cyclical leg movements, activity of the legs is coupled. Apparently, the legs *listen* to each other, so that activity in one leg can be used to affect activity in the other. To establish if during walking, activity in one leg can be manipulated by letting the contralateral leg *work harder* (of less hard), the Lokomat can be used. The Lokomat is a robotic device, consisting of an actuated gait orthosis with integrated computer-controlled linear actuators at each hip and knee joint, a body weight support system, and a treadmill. The Lokomat allows the level of movement support (so-called *guidance*) to be set independently for each leg. This makes it possible to systematically vary the contribution of the individual legs to the production of gait. By measuring muscle activity under these conditions, it can be determined if *harder work* by one leg facilitates activity in the other. If the results provide evidence for this idea, future training protocols may exploit these properties and stimulate activity in the paretic leg by manipulating activity in the other, (non-paretic) leg.

Study objective

Primary Objective: To establish the effect of asymmetrical guidance provided by the Lokomat exoskeleton on levels of muscle activity in persons with post stroke hemiparesis.

Secondary Objective(s): (i) To establish if the abovementioned effects (see primary objective) depend on gait speed (ii) To establish if the abovementioned effects (see primary objective) differ between the affected and unaffected leg of patients.

Study design

Participants will be required to walk in the Lokomat while electromyography (EMG) will be used to record activity of both legs from the following 5 muscles: (1) Vastus medialis (2) Rectus femoris, (3) Biceps femoris, (4) Gastrocnemius medialis and (5) Tibilis anterior.

During Lokomat walking, guidance will be set to either 30% or 100%, for each leg separately, resulting in symmetric (both legs received 30 or 100% guidance) or asymmetric (one leg received 30 and the other 100% guidance) trials at two treadmill speeds (1 or 2 km/h). During the first eight trials, a unique combination of treadmill speed and guidance will be presented. After this, the same eight trials are presented for the second time in the reverse order resulting in a total of sixteen trials performed in the Lokomat. In addition, both speed levels will also be presented outside the exoskeleton on the treadmill (two trials). So, a total of eighteen trials will be performed.

Intervention

A total of 20 (2 for each muscle; 10 per leg) self-adhesive electrodes will be placed on the skin of the participants.

Study burden and risks

Participation in this study is without any risk.

Walking in the exoskeleton may be somewhat fatiguing to some people, when extremely low treadmill speeds (< 2km/h) 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 an *emergency-stop*, which will halt the treadmill and the exoskeleton 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, the patient*s physiotherapist will also be present. The therapist is certified for making adjustments to, and training with the Lokomat, and can provide instructions to the patient for easier progress of the test, or can relieve 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 on whether asymmetrical training can be a useful training strategy in the treatment of gait problems in this population.

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. A first unilateral stroke (infarction or haemorrhage).
2. At least three months post onset.
3. A unilateral paresis of the leg.
4. A Functional Ambulation Categories Score (FAC) of 2 (*Patient requires manual contact of

one person during ambulation on level surfaces*) to 5 (*Ambulation is independent on unlevel and level surfaces, stairs, and inclines*).
5. Patient should be 45 - 70 years old at the time of inclusion
6. Written informed consent

Exclusion criteria

1. Severely impaired cognitive functions (Mini Mental State Exam score *25).
2. Severe speech, language or communication disorders (it will be 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 of 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. Polyneuropathy (clinical judgement)
7. Co-morbidity that can affect the results of the study (e.g. pre-existent problems in leg function or a progressive neurological disorder).
8. Participation in other scientific studies.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-12-2017
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	31-10-2017
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL63078.042.17