Can bilateral functional electrical stimulation (FES) of the calf muscles improve ankle push-off during gait in people with Multiple Sclerosis? A proof of principle study

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Aim of this proof of principle study is to develop a reliable and safe application of bilateral FES of the calf muscles to facilitate insufficient push-off in patients with MS and to assess the preliminary effects of FES on net ankle power...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON41160

Source
ToetsingOnline

Brief title
FES in MS

Condition

- Central nervous system infections and inflammations

Synonym
Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: St MS Research

Intervention

Keyword: functional electrical stimulation, Multiple Sclerosis, push-off, walking

Outcome measures

Primary outcome

In patients with MS, within-subject changes in energy cost of walking, net

ankle power and walking speed will be assessed between the conditions with FES

and without FES.

Secondary outcome

N.A.

Study description

Background summary

The majority of patients with MS experience difficulties in daily activities and walking, and gait impairments can already be seen in the early stage of MS. Within 15 years of diagnosis, nearly 50% of the patients requires assistance with a walking aid, and 10% will be wheelchair dependent. A recent PhD-study of Kempen (2013) aiming to classify distinctive gait patterns of patients with MS has shown that reduced ankle push-off is a large contributor to the decline in walking ability. In patients classified as moderately impaired walkers the majority showed an inadequate push-off (90% right leg and 100% left leg).

Study objective

Aim of this proof of principle study is to develop a reliable and safe application of bilateral FES of the calf muscles to facilitate insufficient push-off in patients with MS and to assess the preliminary effects of FES on net ankle power generation and energy cost of walking.

Study design

This proof of principle study consists of various experiments in healthy participants and in patients with MS. Because of the physical strains, experiments will be carried out in the first place in healthy participants. Next, due to the variability of gait in patients with MS, most experiments will be validated in patients with MS.

Intervention

Functional Electrical Stimulation of the calf muscles

Study burden and risks

The majority of patients with MS experience difficulties in daily activities and walking, and gait impairments can already be seen in the early stage of MS. Within 15 years of diagnosis, nearly 50% of the patients requires assistance with a walking aid, and 10% will be wheelchair dependent. A recent PhD-study of Kempen (2013) aiming to classify distinctive gait patterns of patients with MS has shown that reduced ankle push-off is a large contributor to the decline in walking ability. In patients classified as moderately impaired walkers the majority showed an inadequate push-off (90% right leg and 100% left leg). Because the development of the stimulation algorithm is time-consuming and requires substantial walking effort of the participants, healthy persons will be used in the first phase of the study. In the second phase, patients with MS will be recruited to test the developed algorithm, and to investigate the preliminary clinical relevance.

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

Five healthy subjects and five patients with MS with reduced ankle push-off as shown by 3D gait analysis will be recruited. In order to be eligible to participate, only ambulatory adults (18-65 years) will be invited.

Exclusion criteria

FES is absolutely contraindicated for participants with a cardiac pacemaker. The electrical impulses may lead to disturbances of the pacemaker sensors which could cause a life-threatening situation. Pregnant women will also be excluded from participation. Dysaesthetic sensation of pain, skin injuries or open sores in the area of calf stimulation should be checked as a potential criterion for exclusion.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-02-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Functional Electrical Stimulation (FES)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL49823.029.14