Transcranial magnetic stimulation (TMS) to predict balance and gait patterns following supratentorial stroke.

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

Summary

ID

NL-OMON29916

Source
ToetsingOnline

Brief title
TMS in predicting balance and gait after stroke.

Condition

- Central nervous system vascular disorders

Synonym
Cerebrovascular accident- stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Klinische Fellowship 60-60500-98-041;Zon MW

Intervention

Keyword: gait pattern, prediction, stroke, transcranial magnetic stimulation

Outcome measures

Primary outcome

Basic functions (including their kinetic and kinematic reflections during

standing and walking) of the lower leg muscles.

Secondary outcome

Berg Balance Scale, Fugl-Meyer Motor assessment, Rivermead Mobility Index,

self-selected and maximum walking speed, Functional Ambulation Categories.

Study description

Background summary

Standing and walking require highly integrated sensorimotor and higher perceptual functions of the nervous system. A supratentorial stroke may impair these functions, causing more or less severe postural imbalance and walking disability. Recent longitudinal research concerning ambulation after stroke demonstrates that the early-developed hemiparetic movement patterns do not significantly change over time. These results suggest that it should be possible to make early predictions of hemiparetic balance and gait patterns based on more detailed measures of stroke-related primary impairments of distal leg muscles.

Early individual prediction of balance and gait patterns is of great importance for the optimalisation of rehabilitation strategies. For example, in the case of expected poor recovery, measures to support ankle-foot functions such as individually tailored orthoses or various ways of (non)invasive neuromodulation are warrented to promote independence and to prevent secondary consequences (muscle stiffness and contractures).

Because many problems of standing and walking after stroke originate from weakness and muscular imbalance at the ankle foot level, this research project mainly focuses at understanding and predicting the functions of the lower leg muscles. Recent technical advances have made it possible to better discriminate between essential inputs (corticospinal, reflexes) that drive the spinal

motoneurons essential to human standing and walking.

Study objective

The basic question of this project is to what extent the (long term) functional behavior of critical paretic lower leg muscles during standing and walking can be understood and predicted by (early) assessment of the integrity of the corticospinal connections to these muscles in patients with supratentorial stroke.

Study design

Study I. Transcranial magnetic stimulation of lower leg muscles.
The first step in the proposed research project is to optimize and standardize the method of TMS of the lower leg muscles by using a double-cone coil. This part of the study will be conducted in a sample of 10 patients with chronic supratentorial stroke involving the leg and 10 healthy age-referenced (elderly) subjects. Additionally, five of the chronic stroke patients will undergo the gait and balance protocol as delineated below, in order to test the protocol for study II.

Study II. Transcranial magnetic stimulation in predicting hemiparetic balance and gait patterns in acute stroke.
A cohort study will be conducted of 50 acute patients with a CT or MRI proven first-ever supratentorial stroke. TMS at week 1-2 and at week 6. At week 6, 12 and 24, clinimetry, gait analysis and posturography.

Study III. Relationship corticospinal dysfunction and spastic gait in patients with hereditary spastic paraparesis (HSP). Cross-sectional study in 10 HSP patients, in whom TMS will be used to explain the spastic gait.

Study burden and risks

The main burden in this study arises from the TMS in the second week post stroke. However, TMS is a noninvasive procedure with no risks, if patients are properly included (see exclusion). TMS is applied in some acute stroke patients in regular practice to gain prognostic information.

The gait analysis and the posturography is relatively time-consuming for the patients, but not incrimating. These investigations are often experienced as extended therapy sessions.

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

10 chronic stroke patients (6 months post stroke) with pertaining paresis of the leg and walking disabilities (for study I) .
10 patients with hereditary spastic paraparesis (Study II).
50 (sub)acute stroke patients with initial leg paresis (Brunnstrom stage II-IV; MRC1-3/5)(for study III).

Exclusion criteria

Patients with poor prognosis for survival after the stroke (loss of consciousness, severe CT-anormalities, severe co-morbidity); patients with a history of craniotomy, epilepsy, cardiac prothetic valve, pacemaker implantation, severe polyneuropathy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL12838.091.06