The onset of walking and freezing in Parkinson patients compared to controls: A combined EEG-EMG study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON42689

Source
ToetsingOnline

Brief title
Walking and freezing in PD

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's disease

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: EEG-EMG, freezing of gait, Parkinson's disease, walking

Outcome measures

Primary outcome

Measures of cortico-cortical, cortico-muscular and musculo-muscular coupling (derived from dynamic coherence analysis) during the different tasks, compared between patients with and without FOG and controls. In addition, measures of gait such as step duration, gait velocity and walking rhythm during the different tasks, compared between patients and controls.

Secondary outcome

NA

Study description

Background summary

Freezing of Gait (FOG) is a frequent and disabling feature of Parkinson*s Disease (PD), that is characterized by an inability to walk, which can occur e.g. at the start of walking, when turning, in confined spaces such as doorways or even mid-walking in open spaces in more severe cases. The pathophysiology of FOG is unknown. Most neuroimaging techniques have difficulties measuring brain signals during walking, making it difficult to study the underlying neural substrates responsible for FOG. With the new wireless combined EEG-EMG technique we can measure brain and muscle activity while participants walk under ecologically valid circumstances, hopefully leading to more understanding regarding the neural control of locomotion and FOG in particular.

Study objective

The primary objective is to study how brain and muscles work together during the onset of walking, during turns and during prolonged walking and whether there are differences between healthy individuals and PD patients with and without FOG. Secondary objectives are to evaluate the differences in step duration, gait velocity and walking rhythm between PD patients with and without

FOG and healthy controls, the role of motor timing in walking and FOG and the influence of dual tasking in walking and FOG.

Study design

Observational study.

During the tasks electrical brain activity will be registered using 32-channel EEG integrated in a cap. EMG will be recorded simultaneously from different leg muscles. Furthermore, inertial measurement units (IMUs; integrating accelerometers, gyroscopes and magnetometers in a matchbox-like container) will be placed on the shank to allow movement analysis. After measurement preparation the participant has to perform the following tasks:
1. Repeated 10 meter walk test (at their own pace)
2. Repeated 6 meter walk-turn-walk test (at their own pace)
3. Straight-line walking during approximately 3-5 minutes (at their own pace)
4. Synchronization-continuation task; this task is used to quantify how accurate participants can time their steps to a rhythmic auditory beat (synchronization phase) and then maintain this rhythm after the external auditory cue is extinguished, where performance depends on an internal representation of the beat (continuation phase).
5. Dual task (walking and e.g., counting backwards by 3*s or executing a verbal fluency task), which is expected to induce FOG.

Other parameters of interest (medication use and comorbidities) will be collected from the patient*s file. Moreover, participants will be videoed during task execution to allow visual analysis of the walking pattern and identification of FOG, according to the clinical gold standard.
The study will consist of a pilot study and a case-control study in which PD patients with and without FOG will be compared to healthy age- and sex-matched controls.

Study burden and risks

There are no risks or benefits, and the burden is limited to the time invested in the test (approximately 2 hours, with breaks).

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

Healthy individuals:
o Perceived healthy
o Age >= 18 years, age- and sex-matched with PD patients without FOG for case-control study
o Right-handed according to the Annett Handedness scale
o Written informed consent
All PD Patients:
o able to walk properly (Hoehn & Yahr scale: Stage 2-3)
o PD diagnosis according to the UK Parkinson*s Disease Society Brain Bank criteria (A.J. Hughes, 1992)
o Age < 70 (to limit the presence of vascular problems)
o Right-handed according to the Annett Handedness scale
o Written informed consent
PD patients without FOG:
o self-reported absence of FOG
o Score=0 on (Dutch translation of) Giladi*s FOG questionnaire (Giladi et al., 2000)
o Absence of FOG on clinical examination during rapid bidirectional 360* turns and dual tasking (Snijders et al., 2012)
PD patients with FOG:
o self-reported FOG

o Score >=1 on (Dutch translation of) Giladi*s FOG questionnaire (Giladi et al., 2000) or presence of FOG on clinical examination during rapid bidirectional 360 degree turns and dual tasking (Snijders et al., 2012)

Exclusion criteria

All participants
• Mini Mental State Examination (MMSE) score <26 (to exclude low task performance due to cognitive disabilities)
• (other) neurological or motor disorder (for patients: other than PD)
• Use of medication influencing movement (for patients: other than for PD)
PD patients
• Tremor-dominant PD

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2016
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO

Date:	15-12-2015

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	NL55519.042.15