Postural instability and gait disability: related but separable manifestations of Parkinson*s disease

Published: 10-01-2013
Last updated: 15-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40055

Source
ToetsingOnline

Brief title
Postural instability versus Gait disability in PD

Condition

- Other condition

Synonym
Parkinson's Disease

Health condition

Movement disorders, Parkinson's disease, postural instability and gait disorders

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Princes Beatrix Fonds grant;Rubicon grant

Intervention

Keyword: Gait disorders, Parkinson's Disease, Postural instability

Outcome measures

Primary outcome

To avoid confounding influences of actual movements, subjects are instructed to mentally simulate the act of swaying and walking, but without actually performing it (*motor imagery*). To characterize the neural circuit underlying gait control in PD, we use a validated motor imagery protocol. To characterize the neural circuit underlying postural control, we extend this approach and apply a newly developed protocol for motor imagery of balance that closely matches the protocol used for gait. Specifically, we will use a dynamic balance task (imagining to sway on a balance board), because this is clinically more relevant than static balance. By asking subjects to alternately imagine walking or sway, we can directly contrast and isolate the neural substrates of gait and postural control. Finding differences in neural substrate between gait and balance would have great fundamental and clinical implications. First, this would imply that gait impairment and postural instability result from different pathologies in the brain. Second, this would help to create a model for designing specific therapeutic approaches that are required to combat each of these
symptoms.

Secondary outcome

Secondary parameters include:

- Comparing the brain activity of PD patients with balance impairments and a

group of healthy subjects while they mentally imagine swaying

- Using clinical and objective assessments of gait and balance as covariates in

the analyses.

Study description

Background summary

Postural instability and gait disturbances are among the most incapacitating features of Parkinson*s disease (PD), both for patients and their caregivers. Better pathophysiological insights are needed to provide a rational basis for improved treatment strategies. It is widely assumed that the neural substrate is identical for gait and balance problems. We propose a new pathophysiological scenario, suggesting that although gait impairment and postural instability may temporally coincide in PD, they have distinct neural substrates.

Study objective

The primary objective of this study is to compare the brain activity of PD patients with prominent balance or gait impairments while they mentally imagine swaying or walking respectively.

A secondary objective of this study is to compare the brain activity of PD patients with balance impairments and a group of healthy subjects while they mentally imagine swaying.

Study design

We will test the hypothesis according to which gait and balance have distinct neural substrates using functional magnetic resonance imaging (fMRI) to document brain activity during task performance.

Study burden and risks

The experimental protocol will consist of clinical assessments, performance of

a gait and a balance task and imagination of the performed gait and balance tasks while in an fMRI scanner. These measurements will be performed on two separate mornings, within one week. These two mornings, the patients will arrive in a practically defined OFF state, that is 8-12 hours after withdrawal of antiparkinsonian medication (Langston et al., 1992). By the end of the experiment, medication intake will be resumed according to each patients' prescription. During the time of medication withdrawal, a resurgence of the parkinsonian symptoms is very likely, which might cause discomfort for the patients. However, the experiment including the fMRI measurement do not pose any risk, if appropriate precautions are taken. The noise and the relative confined space of the MRI scanner may however cause some discomfort to some subjects.

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

Parkinson's disease patients
• Men/women of age > 18 years.
• written informed consent
• idiopathic PD, according to the UK Brain Bank Criteria.
• disease severity 2.5, 3 or 4 on the Hoehn & Yahr scale (gait and/or balance disorders but still able to walk/stand independently.;Controls
• right-handed men/women of age > 18 years
• written informed consent

Exclusion criteria

Parkinson disease patients
• patients with levodopa*induced gait or balance disorders (e.g., levodopa*induced freezing of gait). We will therefore exclude patients who score greater on levodopa than off levodopa on the gait, balance or freezing items of the UPDRS.
• failure to lay still for 90 minutes in the scanner (for example due to head tremor or medication-induced excessive movement)
• failure to stand/walk independently
• other causes of clinically relevant gait difficulties (eg, orthopedic or vestibular disorders)
• contra*indications for MR scanning (eg, clautrophobia)
• other neurological disorders such as stroke in history or a psychiatric disease
• depression
• cognitive impairment (MMSE <26).
• severe comorbidity (eg cancer)
• pregnancy
• poor eyesight;Controls
• failure to lay still for 90 minutes in the scanner (for example due to head tremor or medication-induced excessive movement)
• failure to stand/walk independently
• causes of clinically relevant gait/balance difficulties (eg, orthopedic or vestibular disorders)
• contra*indications for MR scanning (eg, claustrophobia).
• any neurological disorders such as stroke in history or a psychiatric disease
• depression
• cognitive impairment (MMSE <26).
• severe comorbidity (eg cancer)
• pregnancy
• poor eyesight

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-05-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2014
Application type:	Amendment
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

ID: 25618
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL41481.091.12
OMON	NL-OMON25618

Study results

Date completed: 31-12-2015

Actual enrolment: 45

Summary results
Trial is onging in other countries