

Waarom blokkeren sommige Parkinson patiënten tijdens het lopen?

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23006

Source

Nationaal Trial Register

Health condition

Parkinson's disease with and without Freezing of Gait, healthy controls.

Sponsors and support

Primary sponsor: University Medical Center Groningen
University of Groningen

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

First primary outcome: Performance of Parkinson's disease patients with Freezing of Gait on behavioral tasks compared to Parkinson's disease patients without Freezing of Gait and healthy controls.

Second primary outcome: Cerebral activation patterns during shifting between response sets

in Parkinson's disease patients with Freezing of Gait, relative to Parkinson's disease patients without Freezing of Gait and healthy controls.

Third primary outcome: Change of performance on response shifting task and gait trajectory after administration of Methylphenidate in Parkinson's disease patients with Freezing of Gait, relative to placebo.

Fourth primary outcome: Cerebral activation change after administration of Methylphenidate in Parkinson's disease patients with Freezing of Gait, relative to placebo.

Secondary outcome

First secondary outcome is the performance on the motor tasks of all groups, compared to the performance on the cognitive task and dual task, by comparing the number of correct responses.

Second secondary outcome is the cerebral activation pattern during shifting between motor task compared to the cerebral activation patterns during shifting between cognitive tasks and during dual tasks in all groups.

Study description

Background summary

Background:

Freezing of gait (FOG) is common in Parkinson's disease (PD). The underlying mechanism of FOG is however unknown. It was hypothesized that PD patients with FOG are unable to keep different tasks (motor or cognitive) on-line and can not flexibly shift between response sets. Whether shifting impairments underlie the mechanism of motor freezing has never been investigated.

Impairments in set-shifting have been associated with a reduced activation in the fronto-striatal circuits in PD. Thus, if impairments in shifting between response sets underlie motor freezing there may be a close inter-relationship between the fronto-striatal circuitry disturbances underlying both shifting impairments and motor freezing.

Treatment options are insufficient to relieve FOG in PD. Recently, Methylphenidate (MPH) has been introduced as a treatment option. No randomized, clinical controlled trial has been performed to investigate the efficacy of MPH for FOG in PD.

Furthermore, there is no understanding of the neural mechanism by which MPH ameliorates cognition and gait in PD. Studies suggest that the neural effects of MPH vary according to task requirements. In healthy controls MPH modulated the striatal activity when response shifting was required.

Objectives:

To investigate whether impairments of shifting between response sets underlie motor freezing in PD and to investigate the efficacy and the neural mechanism by which MPH improves gait and cognition in PD patients with FOG.

Study objective

Parkinson's disease patients with Freezing of Gait show impairments shifting between response sets and a reduced activation in brain areas involved in shifting between response sets, relative to Parkinson's disease patients without Freezing of Gait.

Methylphenidate improves gait and the ability to shift between response sets and will lead to a relative increase of activation in the brain areas involved in shifting between response sets in Parkinson's disease patients with Freezing of Gait, compared to a placebo.

Study design

Pilot study: 6 months;

Data collection: 1.5 years;

Data analysis and publication: 1 year.

Intervention

1. Parkinson's disease patients with Freezing of Gait, Parkinson's disease patients without Freezing of Gait and healthy controls will be assessed with a set-shifting task in a behavioral setting and during functional Magnetic Resonance Imaging with simultaneous Electromyography (fMRI-EMG). In addition, gait characteristics will be assessed;
2. Parkinson's disease patients with Freezing of Gait will be treated with Methylphenidate or placebo for three months with a dosage of 1 mg/kg/day. Methylphenidate or placebo will be randomly assigned (50/50);
3. After three months the assessment of gait characteristics and set-shifting in a behavioral setting and during fMRI-EMG will be repeated in Parkinson's disease patients with Freezing of Gait.

Contacts

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Eligibility criteria

Inclusion criteria

Parkinson's disease according to the UK brain bank criteria.

Exclusion criteria

1. Presence of neurological central nervous system disorders other than idiopathic PD;
2. Surgical treatment for idiopathic PD, such as deep brain stimulation;
3. Dementia;
4. Other significant co-morbidity;
5. Contraindications to MRI scanning;
6. Contraindications to the use of Methylphenidate.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-02-2010
Enrollment:	80
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 33147
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1993
NTR-old	NTR2110

Register

CCMO

ISRCTN

OMON

ID

NL28119.042.09

ISRCTN wordt niet meer aangevraagd.

NL-OMON33147

Study results

Summary results

N/A