

Waarom blokkeren sommige Parkinson patiënten tijdens het lopen?

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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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23006

Bron

NTR

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen

University of Groningen

Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

Pilot study: 6 months;

Data collection: 1.5 years;

Data analysis and publication: 1 year.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33147
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1993
NTR-old	NTR2110
CCMO	NL28119.042.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33147

Resultaten

Samenvatting resultaten

N/A