Differences between dopa-responsive and dopa-resistant Parkinson's tremor

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20997

Source
NTR

Brief title
TREMOR-DOPA

Health condition

Parkinson's disease; tremor; fMRI; GABA

Sponsors and support

Primary sponsor: Radboud University Nijmegen
Donders Institute for Brain, Cognition and Behaviour, Centre for Cognitive Neuroimaging
Source(s) of monetary or material Support: Dutch Brain Foundation

Intervention

Outcome measures

Primary outcome

- fMRI activity (cerebral activity related to the onset and the amplitude of each patient’s tremor episodes).

- GABA concentration in the ventrolateral thalamus contralateral to the tremulous arm.

- structural integrity of the mesencephalon contralateral to the tremulous arm.

Secondary outcome

- Cognitive performance on dopamine-dependent and dopamine-independent behavioural tasks.

- Electrophysiological markers of dopa-responsive and dopa-resistant tremor (EMG).

Study description

Study objective

We hypothesize that PD patients with dopa-responsive and dopa-resistant tremor have different tremor-related brain activity, different inter-regional functional connectivity, and different GABA-ergic tone in the thalamus.

Study design

not applicable. Comparison of 2 sessions (intervention vs. placebo).

Intervention

Levodopa-Benserazide (Madopar) 200-50 mg + Domperidone 10 mg.

Contacts

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Eligibility criteria

Inclusion criteria

PHASE 1 (polymography):

- Idiopathic Parkinson's disease according to UK brain bank criteria.

- Mild to moderate disease severity (Hoehn and Yahr 1-3).

- Presence of a clear resting tremor of at least one arm (UPDRS tremor-score >= 2).

PHASE 2 (neuroimaging):

- Dopaminergic therapy with a clear clinical response of non-tremor symptoms (improvement of total limb bradykinesia on the UPDRS >= 20% after 250 mg levodopa-benserazide).

- Dopamine-responsive tremor (improvement of total limb resting tremor score on the UPDRS >= 60% after 250 mg levodopa-benserazide) OR dopamine-resistant tremor (improvement of total limb resting tremor score on the UPDRS <= 20% after 250 mg levodopa-benserazide).

Exclusion criteria

- Neurological or psychiatric co-morbidity (e.g. stroke, depression).

- Severe head tremor or dyskinesias.

- Cognitive impairment (MMSE < 26).

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Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-01-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-01-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40810
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4940
NTR-old	NTR5042
CCMO	NL47614.091.14
OMON	NL-OMON40810

Study results