

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

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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.

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON20997

### Bron

Nationaal Trial Register

### Verkorte titel

TREMOR-DOPA

### Aandoening

Parkinson's disease; tremor; fMRI; GABA

### Ondersteuning

**Primaire sponsor:** Radboud University Nijmegen

Donders Institute for Brain, Cognition and Behaviour, Centre for Cognitive Neuroimaging

**Overige ondersteuning:** Dutch Brain Foundation

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

- fMRI activity (cerebral activity related to the onset and the amplitude of each patient's

tremor episodes).<br>

- GABA concentration in the ventrolateral thalamus contralateral to the tremulous arm.<br>
- structural integrity of the mesencephalon contralateral to the tremulous arm.

## Toelichting onderzoek

### Doel van het onderzoek

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.

### Onderzoeksopzet

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

### Onderzoeksproduct en/of interventie

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

## Contactpersonen

### Publiek

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### Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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  $\geq 2$ ).

PHASE 2 (neuroimaging):

- Dopaminergic therapy with a clear clinical response of non-tremor symptoms (improvement of total limb bradykinesia on the UPDRS  $\geq 20\%$  after 250 mg levodopa-benserazide).
- Dopamine-responsive tremor (improvement of total limb resting tremor score on the UPDRS  $\geq 60\%$  after 250 mg levodopa-benserazide) OR dopamine-resistant tremor (improvement of total limb resting tremor score on the UPDRS  $\leq 20\%$  after 250 mg levodopa-benserazide).

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Neurological or psychiatric co-morbidity (e.g. stroke, depression).
- Severe head tremor or dyskinesias.
- Cognitive impairment (MMSE  $< 26$ ).
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- Severe head tremor or dyskinesias.
- Cognitive impairment (MMSE  $< 26$ ).

## Onderzoeksopzet

### Opzet

|                  |                       |
|------------------|-----------------------|
| Type:            | Interventie onderzoek |
| Onderzoeksmodel: | Cross-over            |
| Toewijzing:      | Niet-gerandomiseerd   |
| Blindering:      | Enkelblind            |
| Controle:        | Placebo               |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 23-01-2015           |
| Aantal proefpersonen:   | 50                   |
| Type:                   | Verwachte startdatum |

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 21-01-2015       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40810  
Bron: ToetsingOnline  
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

## Resultaten