fNIRS Cortical Activation Patterns during Freezing of Gait.

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27658

Bron
Nationaal Trial Register

Verkorte titel
-

Aandoening

Parkinson's disease; Freezing of Gait

Ondersteuning

Primaire sponsor: Donders Institute for Brain, Cognition and Behaviour (Nijmegen)
Overige ondersteuning: Europees Fonds voor Regionale Ontwikkeling (EFRO), Operationeel programma Oost (OPOost)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

change in fNIRS activity (i.e. oxygenated hemoglobin and deoxygenated hemoglobin) relative

to baseline in 10 regions of interest: the sensorimotor cortex, the supplementary motor area, the premotor cortex, the dorsolateral prefrontal cortex and the posterior parietal cortex (in both hemispheres).

Toelichting onderzoek

Achtergrond van het onderzoek

Freezing of gait (FOG) is one of the most debilitating symptoms in Parkinson’s disease (PD). Neuroimaging studies have tried to unravel it’s underlying neural mechanism, but are hampered by severe limitations in study design because subjects need to lay supine and still in scanners. This study proposes to study FOG in real-time by using multichannel functional near-infrared spectroscopy (fNIRS), a mobile neuroimaging technique that has been successfully applied in other gait studies.

Doel van het onderzoek

This is an exploratory brain imaging study, measuring brain oxygenation over 10 regions of interest. Based on the 'cross-talk' hypothesis form Lewis and Barker (2009), we hypothesize that FOG might be associated with increased activity in cognitive cortices (i.e. prefrontal cortex, posterior parietal cortex) and decreased activity in the motor cortices (i.e. sensorimotor cortex, supplementary motor area, premotor cortex) when compared to normal walking.

Onderzoeksopzet

Experiment is conducted during a single visit to the laboratory of Nijmegen

Onderzoeksproduct en/of interventie

25 persons with Parkinson's disease OFF anti-Parkinson medication and 25 controls will perform a walking task while brain activity is measured with fNIRS. The walking task includes passages through narrow doorways and 180 degree turns in order to trigger FOG.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- > 18 years old
- idiopathic Parkinson's disease
- experiencing freezing of gait more than once a day

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- comorbidities that cause severe gait impairments
- comorbidities that interfere with fNIRS recording (i.e. previous brain surgery, structural cerebral lesions)
- inabilty to comply with the protocol (inability to walk 150 m or make a half turn unaided, inability to walk 10 seconds without experiencing freezing of gait, severe cognitive impairments)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	23-09-2019
Aantal proefpersonen:	25
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
Sharing of processed and non-identifiable data will be done using the Donders Institute research data repository in accordance with EU, institutional and publishers' guidelines. Access to shared data is managed by the project leader or the principal investigator. Potentially identifiable data, such as video recordings, will not be shared with others.

Ethische beoordeling

Positief advies

Datum:	12-09-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49479
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8021

Register	ID
CCMO	NL70915.091.19
OMON	NL-OMON49479

Resultaten