Cortical activation patterns measured with functional near-infrared spectroscopy (fNIRS) during freezing of gait triggered by turning and passing doorways in Parkinson's disease.

Published: 05-09-2019 Last updated: 15-05-2024

The main objective of this study is to identify cortical brain regions that show significant altered fNIRS activity during FOG in patients with PD. This is accomplished by considering four secondary objectives. First, we compare the cortical...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON49479

Source ToetsingOnline

Brief title fNIRS cortical activation patterns during freezing of gait.

Condition

Movement disorders (incl parkinsonism)

Synonym

Parkinson's disease; shaking palsy

Research involving

Human

1 - Cortical activation patterns measured with functional near-infrared spectroscopy ... 5-05-2025

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen **Source(s) of monetary or material Support:** Europees Fonds voor Regionale Ontwikkeling (EFRO);Operationeel programma Oost (OPOost)

Intervention

Keyword: Freezing of Gait, functional near-infrared spectroscopy (fNIRS), Parkinson's disease

Outcome measures

Primary outcome

The main study parameter is change in fNIRS activity (i.e. oxygenated

hemoglobin and de-oxygenated hemoglobin) relative to baseline in 10 brain

regions: the sensorimotor cortex, the supplementary motor area, the premotor

cortex, the dorsolateral prefrontal cortex, and the posterior parietal (in both

hemispheres).

Secondary outcome

/

Study description

Background summary

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.

Study objective

The main objective of this study is to identify cortical brain regions that

2 - Cortical activation patterns measured with functional near-infrared spectroscopy ... 5-05-2025

show significant altered fNIRS activity during FOG in patients with PD. This is accomplished by considering four secondary objectives. First, we compare the cortical activation patterns during normal walking, turning and passing doorways (without FOG) between PD patients and healthy controls. Second, we investigate whether activation patterns are different between freezing evoked by a temporal trigger (turning) and freezing evoked by a spatial trigger (passing a doorway). Third, we assess whether cortical activity change prior to a FOG episode, compared to normal walking. Fourth, motor, cognitive and anxiety scores, which may contribute to freezing, will be tested for association with the cortical activity.

Study design

This is an explorative fNIRS-based imaging study measuring brain oxygenation over 10 regions of interest in 25 PD patients OFF anti-Parkinson medication (i.e. following an overnight withdrawal) and 25 healthy controls during a walking task. The walking task will include 180 degree turns and passages through a narrow doorway in order to trigger FOG in PD patients. Apart from fNIRS measurements, motion data from motion sensors and video recordings are collected during the walking tasks. The motion data and video recordings will be used to label the fNIRS data with the different conditions (i.e. standing still, walking, turning, passing doorway, FOG); and to calculate motor scores (i.e. gait parameters and FOG severity). Cognitive and anxiety scores will be calculated based on questionnaires.

Study burden and risks

A visit to Nijmegen to conduct the experiment will take 3 to 3.5 hours in total. The gait task (including turns and passages through doorways) consists of four sessions of 6,5 minutes each. Patients will be examined at the OFF state, i.e. following an overnight withdrawal of their dopaminergic medication. This is expected to yield more FOG episodes, thereby increasing the power of the study and requiring fewer participants. The increase of PD symptoms associated with the OFF state will resolve upon medication intake after the experiments. Physical tiredness which might occur during the walking test is minimalized by allowing participants to rest as long as needed between each session. Persons with PD, and especially those with FOG, are, due to the nature of their disease, at risk for falling. To reduce this risk of falling, a researcher will continuously accompany the participant during walking. There are no risks associated low. The questionnaires are widely used in medical research and are considered to place little burden on the participants.

Contacts

Public Radboud Universiteit Nijmegen

Heyendaalseweg 135 Nijmegen 6500HC NL Scientific Radboud Universiteit Nijmegen

Heyendaalseweg 135 Nijmegen 6500HC NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- idiopathic Parkinson's disease
- experiencing freezing of gait more than once a day

Exclusion criteria

- comorbidities that cause severe gait impairments

- comorbidities that interfere with fNIRS recording (i.e. previous brain surgery, structural cerebral lesions)

- inability 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

Study design

Design

Study type: Observational non invasive			
Masking:	Open (masking not used)		
Control:	Uncontrolled		
Primary purpose:	Basic science		

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2020
Enrollment:	50
Туре:	Actual

Ethics review

Approved WMO	
Date:	05-09-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	28-04-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27658 Source: NTR Title:

In other registers

Register	
ССМО	
Other	
OMON	

ID NL70915.091.19 NL8021 NL-OMON27658