Neural control of breathing in Parkinson's disease: an exploratory study

Published: 18-09-2023 Last updated: 09-11-2024

Primary Objective: To identify disease (Parkinson*s disease) specific alterations in neural

control of breathing by using respiratory neurophysiological techniques.

Ethical review Approved WMO **Status** Recruiting

Health condition type Movement disorders (incl parkinsonism)

Study type Observational non invasive

Summary

ID

NL-OMON56046

Source

ToetsingOnline

Brief title

Neural control of breathing / NEURON-PD

Condition

Movement disorders (incl parkinsonism)

Synonym

Parkinson's, Parkinson's disease

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breathing, Neural control, Parkinson's Disease, Respiratory physiology

Outcome measures

Primary outcome

- Hypercapnic ventilatory response curve (HCVR): HCVR will be determined using the CO2-rebreathing technique.
- Respiratory related evoked potential (RREP): RREP is a measure of cerebral cortical activity elicited by a short inspiratory occlusion.
- Transcranial magnetic stimulation (TMS) diaphragm: TMS is an established tool for investigating the cortical excitability related to breathing.

Secondary outcome

Not applicable.

Study description

Background summary

Parkinson*s disease (PD) is a progressive neurological disorder, characterised by loss of dopaminergic neurons. Respiratory dysfunction is common in patients with PD and can lead to pneumonia, which is a common cause of death in PD. However, the exact mechanism of respiratory disfunction in PD is unknown. The complex process of neural control of breathing may be involved, but this is understudied. This is partly caused by methodological limitations to quantify neural control of breathing. In this study, we will use respiratory neurophysiological methods to determine whether neural control of breathing is impaired in Parkinson*s disease. These techniques are hypercapnic ventilatory response, respiratory related evoked potentials and transcranial magnetic stimulation. This study will test the hypothesis that the neural control of breathing is impaired in individuals with PD compared to healthy subjects.

Study objective

Primary Objective: To identify disease (Parkinson*s disease) specific

2 - Neural control of breathing in Parkinson's disease: an exploratory study 13-05-2025

alterations in neural control of breathing by using respiratory neurophysiological techniques.

Study design

Exploratory cross-sectional study.

Study burden and risks

The risk of this study for the participants is negligible. Subjects do not directly benefit from participating in this study. The scientific benefit of this study is to achieve a better understanding of the neural control of breathing in Parkinson*s disease. The outcomes of this study may give rise to future new treatments in Parkinson*s disease. The burden of the separate study procedures is relatively small: there are no invasive procedures and patients continue their medication as usual. However, the total time of the visit and the collective burden of the experiments may be perceived as strenuous. Therefore, subjects will be explicitly informed about this aspect of the study, and enough breaks will be scheduled in the program.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- Healthy subjects: competent adult volunteers
- Patients: adult patients with Parkinson*s disease with Hoehn and Yahr staging 1 to 3, clinically confirmed by a movement disorder specialised neurologist
- Willingness and ability to understand nature and content of the study
- Ability to participate and comply with study requirements

Exclusion criteria

- Healthy subjects: previous or ongoing diseases of the central nervous system
- Patients: previous or ongoing diseases of the central nervous system, other than Parkinson*s disease
- History of or current psychiatric treatment
- History of or current brain surgery or epilepsy, including deep brain stimulation
- Neuromuscular disorders
- Pre-existing pulmonary disease, such as chronic obstructive pulmonary disease, asthma or pulmonary fibrosis
- TMS incompatibility (metal parts in head or neck, skin allergies)
- Implanted cardiac pacemaker or defibrillator, neurostimulator, cochlear implant or medical infusion device
- Large or ferromagnetic metal parts in the head (except for a dental wire)
- Pregnancy
- Smoking

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 30-10-2023

Enrollment: 30

Type: Actual

Ethics review

Approved WMO

Date: 18-09-2023

Application type: First submission

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

No registrations found.

In other registers

Register ID

CCMO NL84745.091.23