Extensive phenotyping of REM sleep behavior disorder in patients with Parkinson*s disease and Dementia with Lewy bodies

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The objective of this study is to identify clinical and non-invasive neuroimaging markers that are characteristic for RBD in PD and DLB.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sleep disturbances (incl subtypes)
Study type	Observational invasive

Summary

ID

NL-OMON54258

Source
ToetsingOnline

Brief title
REMIND (REM-sleep In Neurological Disorders)

Condition

- Sleep disturbances (incl subtypes)

Synonym
dream sleep behavior disorder, parasomnia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dementia with Lewy bodies, Parkinson's disease, phenotyping, REM sleep behavior disorder

Outcome measures

Primary outcome

Group comparisons (PD/DLB with RBD versus without RBD) and correlation analyses

with RSWA for the total sample will be performed for:

- Clinical characteristics (i.e. motor, psychiatric, autonomous and sleep

symptoms)

- Brain activity during rest, using fMRI

- Brain anatomy in terms of cortical thickness, regional volume and white

matter integrity, using structural MRI and DTI

- Iron content in the substantia nigra and basal ganglia, using quantitative MRI

- Blood and CSF protein values

Secondary outcome

Not applicable

Study description

Background summary

RBD is a condition characterized by episodes with (often violent) enactment of dreams using movements and vocalizations. The RBD episodes take place during REM sleep and relate to the loss of muscle atonia in this sleep stage. Longitudinal studies on patients with RBD demonstrate that the vast majority of them (>80%) develops a neurodegenerative disease, primarily a synucleinopathy, such as Parkinson's disease (PD) and dementia with Lewy bodies (DLB). The presence of RBD in these diseases is associated with a worse prognosis related to faster cognitive decline and early development of dementia in PD and early onset of Parkinsonism and visual hallucinations in DLB. It

remains unclear, however, why only a subset van PD/DLB patients suffers from RBD and how this disorder contributes to the pathophysiology of synucleinopathy and progressive neurodegeneration.

Study objective

The objective of this study is to identify clinical and non-invasive neuroimaging markers that are characteristic for RBD in PD and DLB.

Study design

This is a cross-sectional multicenter study (VUmc, SEIN and Spinoza Centre), in which four patient groups (PD with and without RBD and DLB with and without RBD) will be investigated. Clinical (i.e. motor, psychiatric, autonomous and sleep symptoms) and high resolution MRI, blood and CSF measures will be collected.

Study burden and risks

The burden for participants for inclusion will consist of:
- Signing the informed consent during the first visit (10 min; minimal burden)
- Interview on sleep history (30 min; minimal burden)
- Fill out self-report questionnaire (20 min; minimal burden)
- Polysomnography at home (one night)

The burden for participant after meeting the inclusion criteria will consist of:
- Self-report questionnaires (60 min)
- Visiting the Spinoza Centre (clinical measures and MRI; in total ±4 hours.
In-between sessions there will be breaks. the risks with MRI are low.

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

- Diagnosed with probable or possible DLB according to the McKeith diagnostic criteria or diagnosed with PD according to the Movement Disorder Society clinical diagnostic criteria for Parkinson*s disease. - Being able to read and understand Dutch
- Being able to understand the aim of the study and the study procedure and give written informed consent
- Absence of medication that is known to precipitate RSWA/RBD, particularly the antidepressants venlafaxine, serotonin-specific reuptake inhibitors (SSRIs), mirtazapine and other antidepressant agents (but not bupropion), and medication that is known to reduce RSWA (melatonin).
- Signed statement of eligibility to participate from the treating specialist (e.g. neurologist)

Exclusion criteria

We will include 80 subjects in the final study; we expect that we will lose ~20% during screening due to exclusion criteria listed below, and therefore expect to screen appr. 100 patients. All patients - A history of neurodegenerative disorders that affect the central nervous system other than PD or DLB - A contraindication to MRI (i.e. metal implants, cardiac pacemakers, prior exposition to metal flakes without an X-ray showing absence of embedded metal in the body, claustrophobia or feeling uncomfortable in small, enclosed spaces, being pregnant) - Patients who have received brain surgery for Parkinson*s disease - Unwillingness to be informed of unexpected medical findings After polysomnography - Untreated moderate to severe obstructive sleep apnea (AHI>=15/h) - None or insufficient amounts (< 5 min) of REM sleep

during polysomnography

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-01-2022
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-08-2023
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL74498.029.20