Bruxism and temporomandibular disorders in patients with Parkinson*s disease

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Primary Objective: to investigate the prevalence of bruxism and TMD in PD patients through objective measurements.Secondary Objectives: to identify factors associated with the presence of TMD or bruxism in a PD population.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56565

Source
ToetsingOnline

Brief title
Parkinson's disease, bruxism and TMD

Condition

- Muscle disorders
- Movement disorders (incl parkinsonism)

Synonym
temporomandibular disorders; bruxism

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam (ACTA)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bruxism, Parkinson's disease, Temporomandibular disorder

Outcome measures

Primary outcome

Main study parameters/endpoints: the primary study parameters are the presence of bruxism, and a TMD diagnosis, according to the Diagnostic Criteria for TMD.

Secondary outcome

The following variables will be evaluated: Medication (viz., Levodopa Equivalent Daily Dose (LEDD)), pain (viz., pain severity), psychosocial symptoms (viz., depression, apathy, anxiety, psychotic, impulse control, somatic symptoms), brain function (viz., cognitive function, presynaptic dopaminergic loss), disease progression (viz., disease stage, disease severity), sleep (viz., quality of sleep, REM sleep behaviour disorder, OSAS) and quality of life.

Study description

Background summary

Earlier research shows that there might be a connection between Parkinson*s disease on one hand and teeth grinding, teeth clenching, and jaw joint issues on the other hand. The symptoms that can arise from these conditions can very inconvenient for patients. The knowledge from this research can assist dentists in providing personalized care to patients with Parkinson*s disease who experience teeth grinding, teeth clenching, and or TMD problems, thereby contributing to an improved quality of life.

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Study objective

Primary Objective: to investigate the prevalence of bruxism and TMD in PD patients through objective measurements.

Secondary Objectives: to identify factors associated with the presence of TMD or bruxism in a PD population.

Study design

Study design: Observational case-control study design.

Study burden and risks

During an appointment with the neurologist, patients will be informed about the study. A few days later they will be called by the investigator with the question if they want to participate. Participants will fill out a research questionnaire (±30 min) and be examined clinically (±20-60 min). Subsequently, all eligible patients will be asked to sleep for 5 nights with a one-channel EMG mobile device (Butler GrindCare®) at home, and to keep a diary for 7 days during wakefulness, to confirm the diagnosis of bruxism. Clinical examination will take place at Academic Centre of Dentistry Amsterdam (ACTA) or at Amsterdam UMC, according to the preferences of the participants. Short-term risks of the clinical examination include possible mild muscle pain and fatigue in the masticatory muscles. This will be minimalized through short intermissions when needed. In addition, in some patients, the gel pad of the Butler GrindCare® can cause reversible skin irritation. There are no long-term risks associated with this study. Patients with a pacemaker or Deep Brain Stimulator (DBS) cannot use the Butler GrindCare® and are excluded for that part of the study.

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

- Patients who fulfil the clinical diagnostic criteria for PD.
- Adults (>18 years old)

Exclusion criteria

- Children or adolescents (<18 years old)
- Patients with a pacemaker or DBS (only excluded for using Butler GrindCare®
- Montreal Cognitive Assessment (MoCA) score <18

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	31-05-2024
Enrollment:	470
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2024
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	NL84981.018.23