Bruxism, temporomandibular disorders and consequences 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 and to identify factors associated with a higher risk of developing these symptoms.Secondary objectives: - To investigate the salivary...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON49742

Source
ToetsingOnline

Brief title
Parkinson*s disease, bruxism and TMD

Condition

- Other condition
- Muscle disorders
- Movement disorders (incl parkinsonism)

Synonym
temporomandibular disorders; bruxism

Health condition

tandheelkundig

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit van Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Mondzorg & Parkinson;NVGPT;NWVT

Intervention

Keyword: Bruxism, Parkinson Disease, Temporomandibular disorder, Tooth wear

Outcome measures

Primary outcome

- (Definite) bruxism diagnosis

- TMD diagnosis (according to the Diagnostic Criteria for TMD; DC/TMD)

- Levodopa equivalent daily dose (LEDD)

- Pain intensity (GCPS)

- Tooth wear screening (TWES)

- Depression (BDI-ii)

- Anxiety (PASS)

- Stress (PHQ-15)

- Cognitive function (PD-CRFS and MoCA)

- Disease stage (Hoehn & Yahr)

- Disease severity (Unified Parkinson*s Disease Rating Scale; UPDRS III)

- SCOPA-SLEEP scale

Secondary outcome

- Salivary flow, pH and buffer capacity of saliva

- Tooth wear screening index (TWES)

- Brain imaging, for example presynaptic dopaminergic loss visualized with

DAT-SPECT (if applicable)

Study description

Background summary

The results of a recent questionnaire-based study suggest that bruxism and temporomandibular disorders (TMD) are more prevalent in Parkinson*s disease (PD) patients than in controls. Bruxism and TMD could be influencing patient satisfaction and quality of life, which is already negatively influenced by having PD. This clinical longitudinal study is designed to more objectively confirm the prevalence of bruxism and TMD in PD patients. Furthermore, factors will be identified which influence the association between bruxism and TMD on one hand and for example severity of the disease and medication use on the other hand. An important consequence of bruxism is tooth wear. Therefore, it is helpful to know whether increased tooth wear is present in patients with PD. And also whether the confounder of tooth wear (saliva) deviates from standard values. But most importantly, we need to know more about this possible relation between tooth wear and PD, because tooth wear can negatively influence the quality of life. By increasing awareness of this possible risk, dentists will be able to prevent extensive restorative work.

Study objective

Primary objective: To investigate the prevalence of bruxism and TMD in PD patients through objective measurements and to identify factors associated with a higher risk of developing these symptoms.

Secondary objectives:
- To investigate the salivary flow in patients with PD.
- To investigate whether the salivary flow, the pH, and the buffer capacity in patients with PD is related to the severity of tooth wear and if this is different in patients with(out) bruxism.
- To investigate whether PD patients with bruxism differ in brain pathophysiology compared to PD patients without bruxism.

Study design

Observational study design

Study burden and risks

study procedures will be combined as much as possible with regular visits to the outpatient clinic for movement disorders at the VUMC. During an appointment

with the neurologist, patients will be informed about the study. A week 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 (±40 min). Subsequently, all patients will be asked to sleep for 5 nights with a one-channel EMG mobile device (GrindCare® GC3+) at home and to use the Bruxism app (BruxApp®) during wakefulness, to confirm the diagnosis of bruxism. Patients who already visit the VUmc, and filled in the questionnaires >1 year ago are requested to repeat this procedure (60min). 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 GrindCare® GC3+ can cause reversible skin irritation. There are no long-term risks associated with this study. Patients with a pacemaker cannot use the GrindCare® GC3+ and are excluded for that part of the study.

Contacts

Public
Universiteit van Amsterdam

Gustav Mahlerlaan 3004
Amsterdam 1081LA
NL
Scientific
Universiteit van Amsterdam

Gustav Mahlerlaan 3004
Amsterdam 1081LA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients who visit the outpatient clinic for movement disorders of the VUmc hospital with (presumable) PD.
- Adults (>18 years old)

Exclusion criteria

- Children or adolescents (<18 years old)
- Patients with a pacemaker (only excluded for using GrindCare® GC3+)
- Patients who do not fulfil the clinical diagnostic criteria for PD
- Patients with atypical parkinsonian syndromes
- Montreal Cognitive Assessment (MoCA) score < 21

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:	Recruitment stopped
Start date (anticipated):	25-09-2020
Enrollment:	235
Type:	Actual

Ethics review

Approved WMO Date:	06-12-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-05-2020
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	NL67599.029.19