

Parkinson's disease, bruxism, and its clinical consequences.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON19915

Source

NTR

Brief title

POKI

Health condition

Parkinson's Disease

Sponsors and support

Primary sponsor: Amsterdam University Medical Centre (location VUmc)

Source(s) of monetary or material Support: De Nederlandse Vereniging voor Gnathologie en Prothetische Tandheelkunde (NVGPT); Stichting Mondzorg en Parkinson; Nederlandse Wetenschappelijke Vereniging voor Tandheelkunde (NWVT);

Intervention

Outcome measures

Primary outcome

Probable/definite sleep bruxism and awake bruxism; temporomandibular disorders

Secondary outcome

Several variables will be evaluated: disease stage, disease severity, medication use, cognitive function, neuropsychiatric symptoms, quality of sleep, stimulant use (alcohol, smoking and drugs), reflux, dry mouth.

Study description

Background summary

Primary Objective: To investigate the prevalence of bruxism and temporomandibular disorders (TMD) in PD patients through objective measurements.

Secondary Objectives:

- To identify factors associated with a higher risk of developing the presence of TMD or bruxism.
- 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 are 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 objective

The null hypothesis will be that the prevalence of bruxism and TMD, in PD patients will be higher than in their peers without PD. Also, we hypothesized that factors as medication use, disease severity, psychosocial factors and lifestyle factors are associated.

Study design

1 (+one week)

Intervention

not applicable

Contacts

Public

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Eligibility criteria

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®)
- Patients without an available smartphone (only excluded for using the mobile application BruxApp)
- 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 controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	29-03-2020
Enrollment:	246
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	19-01-2020
Application type:	First submission

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
NTR-new	NL8307
Other	METC VUmc : 2019.143

Study results