The longitudinal relation between hyposmia and other (non-)motor symptoms in Parkinson's disease - an observational study

Published: 31-03-2020
Last updated: 10-04-2024

Overall aim: To examine the association between olfactory function, motor, and non-motor symptoms in a longitudinal cohort of PD patients.Specific objective(s): 1. To determine whether the degree of hyposmia in PD is associated with disease duration...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON49039

Source
ToetsingOnline

Brief title
Follow-up of olfactory function in Parkinson's disease

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Parkinson's disease

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: Motor symptoms, Non-motor symptoms, Olfaction, Parkinson's disease

Outcome measures

Primary outcome

Olfactory function, measured with University of Pennsylvania Smell

Identification Test (UPSIT)

Secondary outcome

-disease duration (years)

-Unified Parkinson's disease Rating Scale - motor score (UPDRS III)

-Mini-Mental State Exam (MMSE)

-Montreal cognitive assessment (MoCA)

-scales for outcomes of Parkinson's disease (SCOPA)-Sleep

-SCOPA-autonomic dysfunction

-SCOPA-psychiatric complications

-Beck Depression Inventory (BDI)

-Beck Anxiety Inventory (BAI)

-Cognitive tests: Digit Span, Stroop Color-Word test, Letter fluency, Category

fluency, Rey's auditory Verbal Learning Test, clock drawing

-Modified Hoehn & Yahr stage

-Body Mass index (length/weight)

-Blood pressure (lying down, 1 min standing, 3 min standing)

-Medication Use (levodopa equivalent dose)

Study description

Background summary

Parkinson*s disease (PD) is a neurodegenerative disorder characterized by a combination of motor and non-motor symptoms (i.e. hyposmia, psychiatric symptoms, cognitive decline, sleeping disorders and autonomic dysfunction). It is a highly heterogeneous disorder, in which the individual disease course is variable and cannot be predicted. Hyposmia (olfactory loss) is highly prevalent (up to 90%) and may precede the first motor symptoms for 5-10 years. In an earlier cross-sectional study (Roos et al, 2019), we observed a correlation between the degree of hyposmia and various motor and non-motor symptoms as well as a marker of presynaptic dopamine neuronal function as assessed with dopamine transporter single-photon emission computed tomography (DaT-SPECT). It is unclear, however, to what extent hyposmia is longitudinally related to the other PD-related (non-) motor symptoms and may be useful as a marker of disease progression.

Study objective

Overall aim:
To examine the association between olfactory function, motor, and non-motor symptoms in a longitudinal cohort of PD patients.

Specific objective(s):
1. To determine whether the degree of hyposmia in PD is associated with disease duration.
2. To determine whether olfactory function is related to other (non-)motor symptoms in PD patients.
3. To examine whether or not baseline hyposmia predicts more rapid disease progression in PD.

Study design

Longitudinal observational study.

Study burden and risks

The risks associated with participation are negligible. For patients still under treatment at Amsterdam UMC, location VUmc, the study visit will be combined with a regular visit to the outpatient clinic for movement disorders, or a home visit. For patients not under treatment at Amsterdam UMC, location VUmc, the study procedure will be performed during a single visit to the hospital or a home visit. The full assessment, including clinical neurological exam (focussing on parkinsonism), evaluation of olfactory function, various

scales and questionnaires, and cognitive testing will take approximately three hours.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

*Included in the baseline cohort with a diagnosis of Parkinson's disease according to the UK PD Society Brain Bank criteria
*Be able to understand the aim of the current follow-up study, understand the study procedure and be able to give written informed consent

Exclusion criteria

*Diagnosis changed from PD to another form of parkinsonism
*Unwillingness to be informed of unexpected medical findings
*Lack of mastery of Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-08-2020
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	31-03-2020
Application type:	First submission
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	NL71019.029.19