Visual problems in Parkinson disease frequently overlooked: study protocol for a multicenter observational, cross-sectional study

No registrations found.

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

Summary

ID

NL-OMON23926

Source
Nationaal Trial Register

Brief title
VIP

Health condition

Parkinson's disease
visual disorders
visual impairment
Screening questionnaire
ophthalmology
non-motor symptoms

De ziekte van Parkinson
Oogheelkunde, oogproblemen
Niet motore symptomen
Vragenlijst

Sponsors and support

Primary sponsor: RadboudUMC

Source(s) of monetary or material Support: Stichting Parkinson fonds

Intervention

Outcome measures

Primary outcome

- validation of screening questionnaire regarding visual problems. We use in depth ophthalmological assessment as gold standard

Secondary outcome

- prevalence of visual problems within PD

- Clinical impact of visual problems

Study description

Background summary

Background: Visual disorders are common in Parkinson's disease (PD). However, the exact frequency and severity of visual problems are not known. Good visual functioning is crucial for patients with PD, because of their need to compensate visually for motor deficits and postural instability . Awareness, early detection and, when possible treatment of visual problems can lead to increased quality of life. Here, we describe the study design of an observational, multi-center, cross sectional study aiming to (1) validate a screening questionnaire to identify PD patients who should be referred to an ophthalmologist for further assessment; to (2) study the prevalence of visual disorders in PD, and to (3) study the severity and clinical impact of different types of visual disorders.

Methods: This study consists of two phases. In phase one, 750 PD patients and 250 healthy controls will be asked to fill out a newly developed screening questionnaire on visual problems. In phase two, a subgroup of responders (n=100) (with the highest and lowest scores on the screening questionnaire) is invited for an extensive neurological and ophthalmological assessment. The in depth ophthalmologic examination will serve as the ¡°gold standard¡± for validating the screening questionnaire. Moreover, these assessments will be used to study associations between visual disorders and clinical presentation in order to gain more insight in it's clinical impact.

Discussion: Our study will create awareness of ophthalmologic problems in PD, and offers a solid starting point for a careful approach to his subject. In clinical practice, the association between ophthalmologic symptoms and PD is far from obvious to both patients and clinicians. Consequently, patients may not adequately report ophthalmic problems themselves, while clinicians may miss many ophthalmologic disorders that can often be treated. Routinely asking patients about visual problems by using a simple screening questionnaire could be an easy solution leading to tailored treatment to prevent complications, to restore mobility, to ascertain independence, and to improve quality of life.

Study objective

Routinely asking patients about visual problems by using a simple screening questionnaire could be an easy solution leading to tailored treatment to prevent complications, to restore mobility, to ascertain independence, and to improve quality of life.

Study design

- phase 1: 750 PD patients screening questionnaire, 250 controls. (ending 31-07-2018)

- Phase 2: 100 PD patients selected for in depth ophthalmological assessment (ending april 2019)

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

phase 1: Parkinson's disease or control (no inclusion criteria for screening questionnaire)

phase 2:

Diagnosis of PD according to the UKPSDBB criteria

The patient must be able and willing to give written informed consent

The patient must be willing to participate in all study related activities and visits

Age of onset Parkinson's disease > 30 years

Stable doses of Parkinson medications ≥ 4 weeks

Current age≥ 60 years

Exclusion criteria

Hoehn and Yahr's Parkinson's staging score ≥ 4

Secondary cause of parkinsonism as detected by history

(e.g. drug-induced parkinsonism)

Secondary cause of parkinsonism as detected by investigation

(e.g. vascular parkinsonism as detected by neuroimaging)

Dementia according to DSM-IV

Major depressive disorder according to DSM-IV

Psychotic disorder(s) according to DSM-IV

Prior brain surgery (except deep brain stimulation)

Previous eye surgery (except phacoemulsification for cataract and artificial lenses)

Blindness in 1 eye

Medication that influences normal visual function other than PD medication. (Detailed information see Appendix 1)

Systemic diseases that may cause eye problems (HIV, DM type I, type II if the patient had ophthalmologic therapy and/or abnormalities at last screening.)

Neurodegenerative diseases other than Parkinson's disease.

History of lesions near the optic chiasm or occipital cortex.

Migraine

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016

Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion Date:	04-12-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42851
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7421
NTR-old	NTR7663
CCMO	NL58535.091.16
OMON	NL-OMON42851

Study results