

Visual Disorders in Parkinson's Disease

Published: 01-11-2016

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

Summary

ID

NL-OMON42851

Source

ToetsingOnline

Brief title

Vision in PD

Condition

- Movement disorders (incl parkinsonism)

Synonym

Parkinsons, Parkinson's disease

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

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

Intervention

Keyword: Motor symptoms, Ophthalmology, Parkinson's Disease

Outcome measures

Primary outcome

Endpoints include both ophthalmological outcomes and clinical outcomes.

Secondary outcome

n.a.

Study description

Background summary

In addition to the characteristic motor symptoms rigidity, bradykinesia, tremor and postural instability, non-motor symptoms are very common in Parkinson's disease (PD) and have a sometimes equally invalidating impact on daily functioning and quality of life. The presence of visual impairments in PD has remained not well studied, both in research and in clinical practice. The exact frequencies, types and severity of visual problems are not known. The impact of visual problems is particularly vexing for patients with PD, because many patients compensate for their motor deficits by guiding their movements visually. Moreover, many visual problems can be treated effectively. Timely recognition of ophthalmological disorders is therefore essential, so that tailored treatment can be installed to prevent complications, to restore mobility, to ascertain independence, and to improve quality of life.

Study objective

The primary aim of this study is to validate a screening instrument for ophthalmologic disorders using full, in depth ophthalmologic assessment as the gold standard. Secondary aims include:

- * To study the severity and clinical impact of different types of ophthalmologic disorders in patients with PD and explore the treatment options.
- * To determine the prevalence of visual disorders in a sample of patients with PD.

Study design

We will perform an observational, cross-sectional study in 30 patients. Patients will be invited for a single day of ophthalmologic and clinical assessment.

Study burden and risks

The burden for the patients consists of coming to Nijmegen one time for the assessments. This will take approximately 6 hours (10am until 16 pm). No assessments that include any risk for the patients will be performed.

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 that were diagnosed with PD by a neurologist at age >30 years at time of diagnosis will be included.

Exclusion criteria

- Previous eye surgery other than phacoemulsification for cataract
- blindness in 1 eye.
- Medication that influences normal visual function other than PD medication¹³ (parasympatholytic function, phenothiazines, sulphonamides, tetracyclines, isotretinoin).
- Systemic diseases associated with eye problems¹⁴ (sjögren*s disease, marfan, myotonic dystrophy, M. Bechterew, M. Wegener).
- History of lesions near the optic chiasm or occipital cortex (e.g. tumor, infarct, bleed); migraine.

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 20-04-2017

Enrollment: 30

Type: Actual

Ethics review

Approved WMO

Date: 01-11-2016

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 06-07-2017

Application type: Amendment

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23926

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL58535.091.16

Study results

Date completed: 01-01-2019

Results posted: 09-12-2019

First publication

09-12-2019