Visual complaints and disorders in patients with multiple sclerosis or Parkinson's disease

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Objectives of the study are:- To investigate the difference in the nature and severity of objective visual disorders between patients with MS or PD who report visual complaints and those who do not report visual complaints.- To investigate the...

Ethical review Approved WMO **Status** Recruiting

Health condition type Neurological disorders NEC **Study type** Observational non invasive

Summary

ID

NL-OMON46434

Source

ToetsingOnline

Brief title

Visual problems in neurodegenerative diseases

Condition

Neurological disorders NEC

Synonym

brain disease, Neurodegenerative diseases

Research involving

Human

Sponsors and support

Primary sponsor: Rijksuniversiteit Groningen

Source(s) of monetary or material Support: Stichting NOVUM en Koninklijke Visio

Intervention

Keyword: Multiple sclerosis, Parkinson's disease, Visual problems

Outcome measures

Primary outcome

The main study parameter is the objective visual disorders.

Secondary outcome

The secondary parameters are the results of the assessments done at Royal Dutch Visio: standardized interviews and questionnaires, visual function assessments, and neuropsychological/perceptual assessments of the patients with visual complaints and a (control) group of patients without visual complaints (MS and PD).

Study description

Background summary

Currently, there is a lack of knowledge, acknowledgement and recognition in research and clinical practice about visual disorders in patients with multiple sclerosis (MS) or Parkinson*s disease (PD). Patients presumably do not get optimal care and will continue to have complaints in daily life.

Study objective

Objectives of the study are:

- To investigate the difference in the nature and severity of objective visual disorders between patients with MS or PD who report visual complaints and those who do not report visual complaints.
- To investigate the relationship between subjective visual complaints and objective visual disorders of patients with MS or PD with or without visual complaints.
- To investigate the relationship between subjective visual complaints, objective visual disorders and cognitive functioning in patients with MS or PD with or without visual complaints.

Study design

Cross sectional

Study burden and risks

The assessments at Royal Dutch Visio are all part of standard care of patients with MS and PD that suffer from visual complaints. A control group of patients without visual complaints will be asked to participate in the same assessments, which take up to 4 hours. The assessments can require some concentration from which a patient can recover after a short break. The risks of the study and the burden on the patients are therefore negligible. Participants know they can refuse or end participation in the study at any time. Traveling expenses will be reimbursed.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

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Elderly (65 years and older)

Inclusion criteria

Patients must be diagnosed with multiple sclerosis or Parkinson's disease. Patients must be 18 years of age or older.

Exclusion criteria

Any health condition or disease (other than multiple sclerosis or Parkinson's disease) that is likely to have significant impact on visual, motor or cognitive functioning.

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: Diagnostic

Recruitment

NL

Recruitment status: Recruiting
Start date (anticipated): 08-01-2019

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 09-05-2018

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 05-10-2018
Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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 NL62728.042.17