New OCT technique in Parkinson's disease.

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	-

Summary

ID

NL-OMON29318

Source
NTR

Health condition

English:
- retinal nerve fiber layer
- optical coherence tomography
- Parkinson's disease

In het Nederlands:
- netvlies
- optical coherence tomografie
- de ziekte van Parkinson

Sponsors and support

Primary sponsor: VU Medical Center
Source(s) of monetary or material Support: Stichting Parkinson Fonds

Intervention

Outcome measures

Primary outcome

The primary objective is to investigate if the RNFL-ac in PD patients differs significantly from the RNFL-ac in healthy controls.

Secondary outcome

1) to investigate if the RNFL-ac can be used to differentiate PD patients from healthy controls.

2) to compare the sensitivity and specificity of the RNFL-ac with RNFL thickness in differentiating PD patients from healthy controls.

3) to investigate local differences in the RNFL-ac of the retina.

Study description

Background summary

Rationale: Parkinson’s disease (PD) is now known to also cause retinal atrophy. Measuring the retinal never fiber layer attenuation coefficient (RNFL-ac) by means of optical coherence tomography (OCT) is a new technique to analyze the scattering properties of the retina as a sensitive measure of retinal atrophy. Using OCT-derived RNFL-ac it might be possible to differentiate PD patients from healthy subjects.
Objectives: The primary objective is to investigate if the RNFL-ac in PD patients differs significantly from the RNFL-ac in healthy controls.
Secondary Objectives are: 1) to investigate if the RNFL-ac can be used to differentiate PD patients from healthy controls. 2) to compare the sensitivity and specificity of the RNFL-ac with RNFL thickness in differentiating PD patients from healthy controls. 3) to investigate local differences in the RNFL-ac of the retina.
Study design: This is a pilot study with an observational cross-sectional design. Patients and controls will be subjected to a clinical neurological exam and a non-invasive ophthalmologic exam consisting of a visual acuity test (with a Snellen chart), an ocular pressure measurement, a slit lamp examination, fundoscopy and OCT (the RNFL-ac can be calculated from OCT data). The study protocol will take one hour and 20 minutes.
Study population: The study population consists of 20 PD patients in (modified) Hoehn and Yahr stage 2 – 4, age 50 - 70 years, recruited from the outpatient clinic of the Sint Lucas Andreas Ziekenhuis (SLAZ) and 20 adult healthy controls, matched for age, sex and ethnicity.
Main study parameters/endpoints: The main study parameter is the RNFL-ac and its association with the presence of PD will be investigated.

Study objective

The Retinal Nerve Fiber Layer attenuation coefficient (RNFL-ac) in patients with Parkinson's disease differs significantly from the RNFL-ac in healthy controls.

Study design

End date: 1-jun-2015

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:

- Clinical diagnosis of PD fulfilling the criteria of the UK PD Brain Bank (Appendix B)

- (modified) Hoehn and Yahr stage 2 – 4 (Appendix C) and a follow up of at least three years after diagnosis of PD.

- Age 50 – 70 years

- Best-corrected vision 20/30 or higher (using a Snellen chart)

- Intra-ocular pressure < 21 mmHg to rule out glaucoma

In order to be eligible to participate in this study, a control subject must meet all of the following criteria:

- Best-corrected vision 20/30 or higher (using a Snellen chart)

- Intra-ocular pressure < 21 mmHg to rule out glaucoma

Exclusion criteria

- Media opacifications

- Concomitant ocular disease (glaucoma, retinal pathology, or pathology of the cornea, lens or optic nerve)

- History of ocular trauma

- History of laser therapy

- Degenerative neurological disease other than PD.

- MMSE < 26 in healthy controls (this is a possible indication of a degenerative neurological disease)

- First degree relative with PD

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	13-12-2014
Enrollment:	40
Type:	Unknown

Ethics review

Positive opinion
Date: 08-12-2014
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44886
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4901
NTR-old	NTR5003
CCMO	NL47617.029.14
OMON	NL-OMON44886

Study results