Normal Optical Coherence Tomography; correlation OCT-measurements of the retinal thickness: central, peripapillary and peripheral in normal subjects.

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The aim of the study is to measure RT (central, peripapillary and peripheral) in normal subjects and study the posibillity to reduce the variabillity of this measurements by normalisation. Futhermore, correlation of RT with axial lenght, gender and...

Ethical review	Approved WMO
Status	Pending
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON30266

Source
ToetsingOnline

Brief title
NOCTrial

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
healthy retina

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: normal subjects, Optical Coherence Tomography, retinal thickness measurements

Outcome measures

Primary outcome

Retinal Thickness and Retinal Nerve Fiber Layer thickness, measured by OCT

Normalised measurements (proprtional measurements)

Secondary outcome

age

gender

lenght

weight

refraction

Study description

Background summary

Optical Coherence Tomography (OCT) is a very sensative method to measure retinal thickness (RT) and retinal nerve fiber layer-thickness (RNFL). OCT is a save, non-invasive and non-contact procedure.
The latest generation OCT-scanners, the Startus OCT; Carl Zeiss Meditec Inc, measures with an axial resolution of 10 micron. The Stratus software package includes serveral scan aquisition- and analysis protocols, futhermore it contains a normative database. Within the normative database there's a large range of retinal thickness measurements; foveal RT 212 ± 20 micron, central foveal RT 182 ± 23 micron. Several studies correlated RT in normal subjecs to axial lenght, age, gender and Body Mass Index (BMI) without consensus of opinion.
Our research group found a normal RT range of 207 ± 20 *m for foveal thickness and 162 ± 22 *m for central foveal thickness, wich differs from the normative database.

Due to this large range in normal RT, more subtle deviations will not be registered as out of the ordinary. To reduce this variability one can calculate propotions, by correlate the RT measurement to an non-pathologic area and probably achieve normalisation of RT measurements.

Study objective

The aim of the study is to measure RT (central, peripapillary and peripheral) in normal subjects and study the posibillity to reduce the variabillity of this measurements by normalisation. Futhermore, correlation of RT with axial lenght, gender and BMI will be studied.

Study design

a Study type: Inventory Observational

b Study design

To recrute healthy subjects, partners and/or companions of patients in our outpatient clinic were approached.

Examination:
-full opthalmic examination
-capillairy blood level of glucose testing by finger prick (exclusion Diabetes Mellitus)
-blood pressure measurement

-OCT-scans

c. amount of subjects: 60, of different age
d. study lenght, 6 months:

1 3 months for inclusion
2 data-management

e. Study department:
Academic Medical Center,Department of Ophthalmology,
dr. F.D. Verbraak, drs. P.H.B. Kok

mw. drs. P.H.B. Kok

Study burden and risks

The OCT-scanner is a safe non-invasive, non-contact procedure.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

No condtions in the eye or in general wich can influence the retinal thickness measurements

Exclusion criteria

Media opacities or other ocular disease on influence on RT measurement

Diabetes Mellitus
Glaucoma

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2006
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

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	NL14695.018.06