Validation of Images with Slit-lamp Integrated Optical coherence tomography

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Ethical review	Approved WMO
Status	Pending
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Observational invasive

Summary

ID

NL-OMON35240

Source
ToetsingOnline

Brief title
VISIO-study

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
structural changes of the eye

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: optical coherence tomography

Outcome measures

Primary outcome

OCT: direct comparison of B-scans, with respect to the quality and the

diagnostic value of the images.

Secondary outcome

practicallity of the examination, examination time and comfort of the pastient

during the examination, additional (diagnostic) value of OCTscans of the

anterior chamber angle and the peripheral retina.

Study description

Background summary

Optical Coherence Tomography (OCT) is an imaging technique used in ophthalmology. The images are detailed cross sectional images, for example, of the cornea, retina or optic nerve head. The obtained measurements give important information about the morphology of a lesion in the eye. This information is used for diagnosis and follow-up.
Recently a new device has been developed. A slit-lamp, used by the ophthalmologist for basic examination, combined with an OCT (slit-lamp integrated OCT; SLSCAN). This new device can be of use in the clinic. The ophthalmologist can examine the abnormality in the eye with the slit-lamp, and simultaneously make an OCT-scan of the exact location of the lesion. An other advantage is that all examinations can be made with one device.

Study objective

Of each new device it is unknown what the validity is and what the differences (advantages and disadvantages) are compared to the daily used devices.
The aim of this study is to answer the question:

What is the validity and are the objective benefits/limitations of the SI-OCT Topcon compared to conventional examinations (slit-lamp biomicroscopy plus OCT

separately) in patients with anterior segment pathology, retinopathy or glaucoma

Study design

Prospective observational study; Evaluation of a diagnostic procedure.

Study burden and risks

The burden to the patient is minimal and consist mainly of the time of examination with the SI-OCT. Following the standard OCT procedure, the SLSCAN will be performed. The SI-OCT procedure carries no known additional risks.

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: with an indication for OCT examination and / or examination with a 3-mirror contactlens;
Volunteers: no ocular pathology
All subjects:18 years of age or older; Willing and able to sign the informed consent, after reading the patient information form

Exclusion criteria

Cognitive disorders;
Media opacities, like cataract, causing unreliable images with the OCT

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):	01-04-2009
Enrollment:	230
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	NL26994.018.09