1050 nm Optical Coherence Tomography of Choroidal Melanocytic Lesions

Published: 27-04-2009
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To evaluate the use of the new generation OCT in detecting retinal and choroidal changes associated with pigmented tumors of the choroid; in particular, transformations of benign lesions into malignant melanomas.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Ocular neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON33058

Source
ToetsingOnline

Brief title
SDOCT & melanomas.

Condition

- Ocular neoplasms

Synonym
melanoma, neoplasma, tumor

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis Prof. Dr. H.J. Flieringa (SWOO)

Intervention

Keyword: choroidal nevus, melanoma, SDOCT

Outcome measures

Primary outcome

Correlation of conventional diagnostics and 1050 nm OCT imaging.

Secondary outcome

- Ophthalmic examination outcome: benign or malignant aspect of lesion.

- Presence of lipofuscin indicates malignancy.

- Autofluorescence outcome: hyperautofluorescence indicates malignancy .

- Ultrasonography: thickness and diameter of the lesion

Study description

Background summary

Prevalence of melanocytic choroidal lesions is about 20% in the Caucasian population. Differentiation between small malignant melanoma and choroidal nevus is rather difficult. Possibly, OCT can detect early stages of transformation of choroidal nevi into malignant melanomas.

Study objective

To evaluate the use of the new generation OCT in detecting retinal and choroidal changes associated with pigmented tumors of the choroid; in particular, transformations of benign lesions into malignant melanomas.

Study design

Observational cross-sectional and longitudinal cohort-study.

Study burden and risks

Patients in this study do not benefit and receive no financial compensation. There are no anticipated major side effects. Study related measurements occur

in combination with regular clinical visits and will take about 40 minutes per visit. There will be 3 visits in 1 year. Total study time is 2 hours. Burden is considered to be low.

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

- Age >= 18 years.
- Informed consent.
- Choroidal melanocytic lesion.

Exclusion criteria

- Media opacities preventing imaging.
- Use of systemic or dermatological infrared-photosensitive medication.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-04-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL26968.078.09