Temporal contrast sensitivity as predictor of visual acuity after cataract surgery

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Ethical review	Not approved
Status	Will not start
Health condition type	Vision disorders
Study type	Observational non invasive

Summary

ID

NL-OMON38468

Source
ToetsingOnline

Brief title
TCS & VA after cataract surgery

Condition

- Vision disorders

Synonym
cataract and/or dry age-related macular degeneration

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Coolsingel;Stichting Achmea Gezondheidszorg;Het Oogziekenhuis Rotterdam

Intervention

Keyword: cataract, dry AMD, post-op visual acuity, temporal contrast sensitivity

Outcome measures

Primary outcome

Temporal contrast sensitivity

Postoperative visual acuity

Secondary outcome

Presence and extent of cataract (LOCS III score)

Presence and extent of AMD (AREDS score)

Preoperative visual acuity

Refractive error

Straylight

Study description

Background summary

When cataract leads to impairment of visual acuity (VA), one of the goals of cataract surgery is to restore VA. Co-morbid eye- or brain disease (e.g. glaucoma, age-related macular degeneration (AMD), retinitis pigmentosa or amblyopia) may preclude optimal VA after cataract surgery. Currently, no objective measurement exists to assess whether impaired VA is solely due to cataract, or at least partly attributable to pathology of retinal or neuronal processing. If such a measurement would exist, it might be possible to more accurately predict VA after cataract surgery.
Temporal contrast sensitivity (TCS) comprises the sensitivity of the visual system to contrast change in time (as opposed to contrast change in space). Studies have shown that TCS decreases when retinal pathology is present, whereas impairment of eye optics (e.g. cataract) have no influence on TCS. This suggests that TCS has high sensitivity and specificity for pathology of retinal or neuronal processing and that a correlation exists between preoperative TCS and optimal VA that is feasible after cataract surgery. If this is true, TCS could be applied to predict postoperative VA in surgically treated cataract

patients.

Study objective

The primary study objective is to assess whether TCS in cataract patients is a predictor of postoperative VA and if so, whether it is a better predictor than currently routinely used measurements, as represented by preoperative VA measurement through multiple pinhole. Secondary objectives are (1) to investigate the influence of disturbed eye optics (cataract patients) and retinal pathology (AMD patients) on TCS, and (2) to assess (intraobserver) repeatability and reproducibility of the TCS measurement.

Study design

Prospective non-interventional cohort study.

Study burden and risks

There are no benefits for the participant. Risks are negligible. Burden comprises two non-invasive measurement sessions lasting approximately 30-60 minutes per session.

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 >= 65
Scheduled for cataract surgery
With or without dry AMD as ophthalmic co-morbidity
Informed consent

Exclusion criteria

Amblyopia
Corneal haze
Guttata
Diabetic maculopathy / retinopathy
Epiretinal membrane
Glaucoma
Uveitis
Opthalmic vessel occlusion
Retinal detachment / defect
Vitrectomy
Trauma
Corneal surgery
Refractive surgery
Cystoid macular edema in other eye
Wet AMD

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:	Will not start
Enrollment:	180
Type:	Anticipated

Ethics review

Not approved

Date:	27-05-2013
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	NL44741.078.13