Straylight as a possible parameter for a Functional Classification System of Posterior Capsule Opacification (FCSPCO) and glare complaints.

Published: 27-09-2007
Last updated: 08-05-2024

- Development of FCSPCO.- Determine if straylight is a reliable parameter for FCSPCO.

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

Summary

ID

NL-OMON30847

Source
ToetsingOnline

Brief title
Functional Classification System of Posterior Capsule Opacification.

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
posterior capsule opacification

Research involving
Human

Sponsors and support

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

Intervention

Keyword: classification, posterior capsule opacification, straylight, YAG laser

Outcome measures

Primary outcome

Retinal straylight.

Secondary outcome

Correlation between FCSPCO and straylight.

Visual acuity (ETDRS).

Contrast sensitivity (Pelli-Robson).

Pupil diameter.

Correlation between straylight and visual acuity.

Correlation between straylight and contrast sensitivity.

Correlation between type of IOL implant and straylight.

Study description

Background summary

Posterior capsule opacification (PCO) is the most common complication after cataract extraction. Visual functioning is affected by retinal straylight which happens to be increased by PCO. Thus far, a classification system of PCO based upon visual function is lacking. The aim of this study is to develop a Functional Classification System of Posterior Capsule Opacification (FCSPCO).

Study objective

- Development of FCSPCO.
- Determine if straylight is a reliable parameter for FCSPCO.

Study design

Prospective, observational case series.

Study burden and risks

Participants do not benefit from the results of this study. Risks are negligible.

Contacts

Public
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland
Scientific
Oogziekenhuis Rotterdam

Schiedamse Vest 180
3011 BH Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Informed consent.
- Age >= 18 years of age.
- BCVA <= 0.50 LogMAR (>= 0.32 Snellen).

Exclusion criteria

- Corneal disorder (e.g. Fuchs* endothelial dystrophy, herpetic keratitis, punctata).
- Cylinder > 3 diopters.
- Severe vitreous opacities.
- Insufficient tearfilm (e.g. Sjögren syndrome); Schirmer test < 5 mm or tear break-up time < 10 s.

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:	Recruitment stopped
Start date (anticipated):	08-02-2008
Enrollment:	350
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2007
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	NL18107.078.07