Is Intentional Continuous Shallowing of the Anterior Chamber (ICSAC) a safe procedure? Does it cause endothelial cell damage?

Published: 24-08-2011
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To compare the effect on the corneal endothelium of ICSAC during vitrectomy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35773

Source
ToetsingOnline

Brief title
ICSAC

Condition

- Eye disorders NEC

Synonym
macular hole/pucker or vitreous opacity requiring vitrectomy

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: corneal endothelium, shallowing of anterior chamber, vitrectomy

Outcome measures

Primary outcome

Endothelial cell density at 1 and 3 months.

Secondary outcome

ECD at 6 months.

IOP.

Depth anterior chamber.

BCVA.

Complications.

Study description

Background summary

Removal of vitreous near sclerotomies without touching the lens is facilitated by intentional continuous shallowing of the anterior chamber (ICSAC). Thus, the risk of sclerotomy related complications can be reduced. It is unknown, however, whether ICSAC poses a risk to the corneal endothelium.

Study objective

To compare the effect on the corneal endothelium of ICSAC during vitrectomy.

Study design

Randomized, comparative, open-label, parallel.

Intervention

ICSAC during vitrectomy versus no ICSAC during vitrectomy.

Study burden and risks

Exclusively study-related assessments are performed during regular visits and take about 20 minutes extra time (i.e. 80 minutes in total); risks involved are negligible. The risk of sclerotomy related complications is supposedly less in the ICSAC group, but the risk of increased loss of endothelial cells may be higher. Treatment of the control group comprises a conventional vitrectomy procedure.

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.
- Requiring vitrectomy for floaters, macular pucker or macular hole.

Exclusion criteria

- Vitrectomy procedure is anticipated to be complicated.
- ECD < 2000 mm-2
- Pseudophakia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2012
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2011
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	NL37200.078.11