

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON26827

### Source

NTR

### Brief title

ICSAC

### Health condition

Macular pucker, macular hole and vitreous opacities requiring vitrectomy.

## Sponsors and support

**Primary sponsor:** The Rotterdam Eye Hospital

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010-4017777

**Source(s) of monetary or material Support:** Stichting Wetenschappelijk Onderzoek Oogziekenhuis "C Prof. Dr. Flieringa (SWOO)

## Intervention

## Outcome measures

### Primary outcome

Endothelial cell density (ECD) at 1 and 3 months.

### Secondary outcome

1. ECD at 6 months;
2. Anterior Chamber Depth at 3 and 6 months;
3. Corneal Topography at 3 and 6 months;
4. Best corrected visual acuity;
5. Intraocular pressure;
6. Gonioscopy;
7. Complications (retinal defects, retinal detachment, etc.).

## Study description

### Background summary

Rationale:

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.

Objective:

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

Study design:

Randomized, comparative, open-label, parallel.

Study population:

Patients requiring vitreoretinal surgery.

Intervention:

ICSAC during vitrectomy versus no ICSAC during vitrectomy.

Main study parameters/endpoints:

Endothelial cell density at 1 and 3 months.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

### **Study objective**

Intentional continuous shallowing of the anterior chamber (ICSAC) does not harm the corneal endothelium.

### **Study design**

Baseline, 1, 3 and 6 months.

### **Intervention**

Vitrectomy with ICSAC versus vitrectomy without ICSAC.

## **Contacts**

### **Public**

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## Eligibility criteria

### Inclusion criteria

1. Age ≥ 18 years;
2. Informed consent;
3. Requiring vitrectomy for floaters, macular pucker or macular hole.

### Exclusion criteria

1. Vitrectomy procedure is anticipated to be complicated;
2. ECD < 2000 mm<sup>2</sup>;
3. Pseudophakia.

## Study design

### Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2011
Enrollment:	50
Type:	Actual

## Ethics review

Positive opinion	
Date:	26-08-2011
Application type:	First submission

## 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
NTR-new	NL2900
NTR-old	NTR3046
Other	OZR / MEC / CCMO : 2009-09 / 2011-259 / NL37200.078.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

Mulder V, Veckeneer M, van Rooij J, Delaey C, van Meurs JC. Intentional continuous shallowing of

the anterior chamber, a procedure to prevent lens touch during phakic vitrectomy. Acta Ophthalmol.

2015; Epub: Aug 13.

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