

# Cataract surgery in eyes with an idiopathic macular epiretinal membrane: the effect on the epiretinal membrane and the surgical outcome

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To quantify progression of macular ERM, and the degree of correlation with phaco-energy, after phacoemulsification.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Eye disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON48514

### Source

ToetsingOnline

### Brief title

Cataract surgery & ERM

### Condition

- Eye disorders NEC

### Synonym

macular epiretinal membrane, macular pucker

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Oogziekenhuis Rotterdam

**Source(s) of monetary or material Support:** Stichting wetenschappelijk onderzoek

## Intervention

**Keyword:** Cataract, Epiretinal membrane, Pars plana vitrectomy

## Outcome measures

### Primary outcome

Progression of ERM and phaco-energy.

### Secondary outcome

Stage of ERM (OCT).

Central foveal thickness (CFT; OCT).

Progression of ERM after phacoemulsification.

Presence of CME (OCT).

Visual acuity (Snellen).

Metamorphopsia (M-charts, see Matsumoto et al. 2003 ).

Indication for vitrectomy and ERM peeling.

Complications.

## Study description

### Background summary

There is, as yet, no consensus among cataract surgeons and vitreoretinal surgeons with respect to the optimal treatment strategy for patients with cataract and an epiretinal membrane (ERM). For ERM-related symptoms, pars plana vitrectomy (PPV) is usually combined with cataract extraction but when cataract surgery is indicated for these patients, the option of phacovitrectomy, although perhaps equally beneficial for some of them, is less often taken into consideration.

### Study objective

To quantify progression of macular ERM, and the degree of correlation with phaco-energy, after phacoemulsification.

### **Study design**

Prospective observational.

### **Study burden and risks**

Participants do not benefit, risks and inconvenience are negligible.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

### **Inclusion criteria**

Age  $\geq$  50 years.

Informed consent.

Senile cataract and idiopathic macular epiretinal membrane, stage 1, 2 or 3, on OCT.

## Exclusion criteria

Secondary macular ERM.

Diabetic retinopathy or other vascular retinopathy.

Pseudoexfoliation syndrome.

Advanced glaucoma (with visual field defects).

Any ocular opacity that may prevent reliable OCT scans.

Any kind of maculopathy such as pucker and severe (subjective) metamorphopsia.

## 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): 16-08-2019

Enrollment: 120

Type: Actual

## Ethics review

Approved WMO

Date: 25-04-2019

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	NL69328.078.19