

# Assessing retinal sensitivity after removing silicone oil

<b>Submission date</b> 19/10/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/11/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/05/2019	<b>Condition category</b> Eye Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The retina is the thin layer at the back of the eye that contains the light-sensing cells. Retinal detachment is when this layer separates from the layer behind that contains blood vessels and other cells that support the survival of the light-sensing cells. Retinal detachment must be treated quickly to prevent vision loss. It is commonly managed by a vitrectomy procedure (removing some of the liquid in the eyeball) with the injection of silicone oil to hold the retina in place while it reattaches to the underlying layer, but the oil may affect retinal function. Therefore removing the oil after the retina has healed might result in improved vision. This study aims to investigate whether the sensitivity of the retina to light is affected by silicone oil by measuring sensitivity before and after silicone oil removal.

### Who can participate?

Participants included any patient who underwent a vitrectomy (retinal surgery) for retinal detachment using a silicone oil tamponade (a heavy oil used to maintain the retina in its place). Participants eyes were examined before and after silicone oil removal.

### What does the study involve?

The study involves a non-invasive investigation called microperimetry to assess retinal sensitivity. It also includes tests of vision and pressure in the eye.

### What are the possible benefits and risks of participating?

Participants might benefit from more explanation of their surgery and more investigation if their sight has worsened. All the tests are non-invasive, so there was no additional risk from participating in the study.

### Where is the study run from?

Cairo University Hospital

### When is the study starting and how long is it expected to run for?

August 2016 to May 2017

Who is funding the study?  
The investigators funded the study.

Who is the main contact?  
Dr Hebatalla Makled, Lecturer of Ophthalmology, Kasr Al-Ainy teaching hospital.

**Study website**

N/A

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Hebatalla Makled

**ORCID ID**

<http://orcid.org/0000-0002-3834-2538>

**Contact details**

Ophthalmology department  
Kasr Al-Ainy hospital  
Faculty of Medicine- Cairo university  
Cairo  
Egypt  
11562

**Type(s)**

Scientific

**Contact name**

Dr Maha Youssef

**ORCID ID**

<http://orcid.org/0000-0003-1637-056X>

**Contact details**

Ophthalmology department  
Kasr Al-Ainy hospital  
Faculty of Medicine- Cairo university  
Cairo  
Egypt  
11562

## Additional identifiers

EudraCT/CTIS number

IRAS number

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## **Study information**

### **Scientific Title**

Retinal sensitivity before and after silicone oil removal using microperimetry

### **Study objectives**

To investigate the effect of silicone oil on the retina through assessment of retinal sensitivity, using microperimetry, before and after silicone removal.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Cairo University Ophthalmology department ethics board, 17/10/2016. No reference number.

### **Study design**

Observational prospective comparative study

### **Primary study design**

Observational

### **Secondary study design**

Prospective comparative

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

No participant information sheet available

### **Health condition(s) or problem(s) studied**

Rhegmatogenous retinal detachment

### **Interventions**

All participants received microperimetry examination one day prior to and one month after silicone oil removal. Silicone oil removal was performed using an infusion-extraction technique with two standard sclerotomies.

During microperimetry, participants were examined in a dark room for 15 minutes with occlusion of the non-tested eye. They were asked to fixate on a central target. A customised pattern centered on the central 11° was used, after auto-correction of patient's refractive error by the machine, with the following features: Goldmann III stimulus size, 200 millisecond stimulus duration, a 1500 millisecond interval between stimuli and a 4 – 2 strategy on a 1.27 cd/m<sup>2</sup>

background.

Retinal sensitivity was tested at 28 points: 4 stimuli at 2.3°, 12 stimuli at 6.6° and 12 stimuli at 11°. The stimulus level ranged between 0 dB and 20 dB. The total retinal sensitivity and sensitivity of each layer (inner, middle and outer) were assessed.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

Retinal sensitivity, assessed using microperimetry one day before silicone oil removal and one month after silicone oil removal.

## **Secondary outcome measures**

The following are assessed one day prior to silicone oil removal and 1 day, 1 week, 2 weeks and 1 month after surgery:

1. Best corrected visual acuity (BCVA), assessed using a Snellen chart and converted into logMAR using statistical analysis
2. Intraocular pressure, assessed using the Goldmann applanation tonometer

## **Overall study start date**

01/08/2016

## **Completion date**

31/05/2017

# **Eligibility**

## **Key inclusion criteria**

1. Macula off rhegmatogenous retinal detachment with any grade of proliferative vitreoretinopathy (PVR)
2. Pars plana vitrectomy (PPV) with silicone oil 5000 as a tamponading agent
3. Aged 18 years or older

## **Participant type(s)**

Patient

## **Age group**

Adult

## **Lower age limit**

18 Years

## **Sex**

Both

## **Target number of participants**

22 (10 patients in group A, 12 patients in group B)

## **Total final enrolment**

22

**Key exclusion criteria**

1. Undergoing vitrectomies for proliferative diabetic retinopathy
2. Recurrent retinal detachments,
3. Macular holes,
4. Chorioretinal degenerations involving the macula
5. Developed the following complications following oil removal:
  - 5.1. Visually significant cataracts
  - 5.2. Secondary glaucoma with intraocular pressure (IOP) exceeding 26 mmHg
  - 5.3. Silicone oil emulsification
  - 5.4. Recurrent detachment
  - 5.5. Hypotony

**Date of first enrolment**

01/11/2016

**Date of final enrolment**

30/04/2017

**Locations****Countries of recruitment**

Egypt

**Study participating centre**

**Kasr Al-Ainy teaching hospital**

Faculty of Medicine- Cairo University

Cairo

Egypt

11562

**Sponsor information****Organisation**

Ophthalmology department, Kasr Al-Ainy hospital, Cairo University

**Sponsor details**

Faculty of medicine

Kasr Al-Ainy street

Cairo

Egypt

11562

**Sponsor type**

University/education

**Website**

www.medicine.cu.edu.eg

**ROR**

https://ror.org/03q21mh05

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

We intend to publish our results in November 2018

**Intention to publish date**

19/11/2018

**Individual participant data (IPD) sharing plan**

All the data used and/or analysed during the current study are available and can be presented by the corresponding author upon a reasonable request from Hebatalla Makled, MD (Lecturer of Ophthalmology, Kasr Al-Ainy Teaching Hospital, Faculty of Medicine, Cairo University) (dr.h.makled@hotmail.com)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	11/04/2019	28/05/2019	Yes	No