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Assessing retinal sensitivity after removing silicone oil

Submission date	Recruitment status	[_] Prospectively registered
19/10/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/11/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2019	Eye Diseases	

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 underlaying 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

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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/m²

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
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11562

Sponsor information

Organisation
Ophthalmology department, Kasr Al-Ainy hospital, Cairo University

Sponsor details
Faculty of medicine
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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?
Results article	results	11/04/2019	28/05/2019	Yes	No