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Is perfluorocarbon and air more effective than perfluorocarbon or air alone when removing emulsified silicone oil following treatment for a detached retina?

Submission date
22/12/2018

Recruitment status
No longer recruiting

Registration date
29/07/2019

Overall study status
Completed

Last Edited
29/07/2019

Condition category
Eye Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The retina is the layer of light-sensitive cells at the back of the eye. Silicone oil has been used for many years in the treatment of torn or detached retinas. It is injected into the eyeball to prevent fluid flowing across holes in the retina. However, silicone oil can create problems in the eye if it becomes emulsified (forms small bubbles suspended in water-based liquids) and must be removed as completely as possible once the retina has healed. If the removal procedure does not remove all of the silicone oil, patients might experience these problems and might also be able to see silicone bubbles blocking their vision. The removal involves a surgical procedure in which air is injected to stir up the liquids inside the eye. Then a perfluorocarbon liquid can be injected to displace the silicone oil so that the mixture can be sucked into a syringe and removed. This study aims to compare whether using air alone or air followed by perfluorocarbon liquid removes the most silicone oil.

Who can participate?
People who have been treated for a retina condition using silicone oil and are having the silicone oil removed.

What does the study involve?
The participants will be randomly allocated to one of two groups. They will all undergo the silicone oil removal procedure. For one group, only air will be used and in the other, air followed by perfluorocarbon liquid will be used. Samples of the fluid that is removed from the eye will be tested to measure how much silicone oil has been removed.

What are the possible benefits and risks of participating?
The proposed technique is more effective for emulsified silicone removal with less intraocular turbulence of the irrigation fluid that can damage the retina, as the retina is covered with PFLC liquid. The main adverse events is the redetachment that can occur in any group that will be treated with repeated silicone oil tamponade.

Where is the study run from?
S. Fyodorov Eye Microsurgery State Institution (Russia)

When is the study starting and how long is it expected to run for?
October 2017 to March 2019

Who is funding the study?
The investigators will pay any additional costs of the study.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1957

Study information

Scientific Title
Novel surgical technique of emulsified silicone oil removal

Study objectives
Emulsified silicone oil removal with the simultaneous use of perfluorocarbon and air is better than the emulsified silicone oil removal with the use of perfluorocarbon or air separately

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics of the S.N. Fedorov NMRC "MNTK" Eye Microsurgery Institute, 25/10/2017, ref: 81.4

Study design
Prospective multicentre interventional controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Removal of silicone oil following treatment of vitreoretinal disorders.

Interventions
The study should include at least 10 to 20 patients from each center with any period of silicone tamponade after rhegmatogenous retinal detachment repair that are considered for silicone oil removal.

The participants are randomized into two groups. In both groups the intraocular fluid (IOF) should be obtained before and after washing the vitreous cavity by 25G aspiration cannula and simultaneous tamponade with air. The surgical approach is based on 25-gauge pars plana silicone oil removal. Irrigation of balanced salt solution is supplied under the pressure of 20-30 mm Hg (in the range). The retrobulbar block is done for akinesia and anesthesia supply. After three transconjunctival port incisions are made, the continuous infusion is installed in the inferior temporal segment approximately 3.5 mm away from the limbus. The main portion of SiO (silicone oil) is extracted through the side port by active aspiration. An extrusion cannula is injected in the mid-posterior vitreous cavity with the assistance of an endoilluminator. For the fluid/ air exchange, simultaneously 4 ml intraocular fluid with the remaining emulsified silicone oil (ESiO) is aspirated with a 5-ml syringe with an endovitreal long-tipped cannula. This is the sample used for investigation. The aspirated intraocular fluid is immediately poured into two wells of a sterile plastic 24-well culture plate with an inverted marking of 5 areas on the inside surface of the bottom. Air/fluid exchange is than applied with simultaneous continuous irrigation of balanced salt solution under increased pressure (30-40 mm Hg) with continuous air aspiration with gradual and partial elevation of the extrusion cannula on the very surface of the intraocular liquid in the direction to anterior chamber. During this procedure, the irrigation port is turned away from the macular region and optic nerve. This step is important to exclude the traumatic influence of the infusion to the retina and to create turbulence of the fluid that mobilizes ESiO particles especially from an anterior part of the posterior segment of the eye. Once the gas is completely removed, active injection of perfluorocarbon (PFCL) is applied until its level fills half of the vitreous cavity. The procedure is then followed by fluid air exchange without PFCL aspiration by locating the extrusion cannula at the anterior part of the vitreous cavity. The air bubble is formed by positioning the cannula partially in the air-liquid interface and gradually moving its posteriorly till a small liquid interface is left between the air and PFCL. The extrusion cannula is then located in the central part of the layer of residual liquid between air and PFCL until the liquid is completely removed. The eye globe is moved in different directions with the mechanical force applied on the scleral ports. The peripheral parts of the vitreous cavity

is checked for fluid and remnants of ESiO and is removed with the extrusion cannula in the air-PFCL interface. ESiO is removed from the surface of PFCL as well. PFCL is extracted in the same fashion by the extrusion cannula that is gradually and partially dipped on the surface in the central part of PFCL. If needed the sequence of steps can be repeated. Irrigation of balanced salt solution is supplied under a pressure of 20-30 mm Hg with continuous gas aspiration, at the same time, a fluid with the remaining ESiO is aspirated with the 5-ml syringe with an endovitreal long tipped cannula – this sample is taken for testing.

The control group underwent the same procedure of vitreous cavity washing but without PFCL usage.

The aspirated IOF was immediately placed in a sterile well plate (60 x 15 mm), with the inverted marking of 5 standardized regions. Sequentially the photo made from 5 corresponding regions of each sample using a light microscope (at magnifications 4x in a standard phase contrast mode (optical microscope IX-81, Olympus, Japan), the qualitative analysis of silicon was carried out using a specialized computer program ImageJ (NIH, Bethesda, USA), during which the analysis of the following parameters were recorded: silicone count, total area, average size, area%. The automated computer program is recently under development for SiO quantification.

Intervention Type
Other

Primary outcome(s)
Quantitative analysis of silicon using an Image J program and an automated computerized program that is currently under development

Key secondary outcome(s))
1. Visual acuity assessed using a Snellen chart on day 1 and after one month.
2. Intraocular pressure measured using pneumotonometry on day 1 and after one month.

Completion date
20/03/2019

Eligibility

Key inclusion criteria
1. Retinal detachment surgery with silicone oil tamponade with silicone oil emulsification
2. Aged 20-90 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Redetachment of the retina

Date of first enrolment
15/01/2018

Date of final enrolment
15/10/2018

Locations

Countries of recruitment
Russian Federation

Study participating centre
S. Fyodorov Eye Microsurgery State Institution
Beskudnikovsky boulevard 59A
Moscow
Russian Federation
127486

Sponsor information

Organisation
S. Fyodorov Eye Microsurgery State Institution

ROR
https://ror.org/04w68cb80

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
S. Fyodorov Eye Microsurgery State Institution

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Daria Dibina (darya.dibina@mail.ru) as an Excel file. Consent from participants was obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes