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5000-centistoke silicone oil is a better choice of intraocular tamponade in complicated vitreoretinal cases

Submission date 12/09/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2017	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/09/2017	**Condition category** Eye Diseases	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Eyes contain a jelly-like liquid called vitreous. When a patient is having surgery on their retina (the part of the eye where light signals are sent to the brain to create an image) this liquid has to be removed in order to gain access. This surgical procedure is known as a plars plana vitrectomy. During this procedure, vitreous needs to be replaced with a saline (salt water). In some cases, the retina can become detached from the eye and so silicone oil tamponade (gel) may be used to keep the retina in place. However, an extended period of SO tamponade is not without its disadvantages. Shear forces caused by eye movements act upon SO, making it disperse to form tiny droplets, resulting in emulsification (break down). Complications of SO usage is highly influenced by emulsification and include moving around the eye, glaucoma (where the optic nerve comes damaged), inflammation (swelling), corneal decompensation (becomes opaque), keratopathy (calcium on the central cornea) as well as cataract. Current studies have shown that the tendency of a substance to emulsify is highly dependent on its viscosity (thickness or stickiness). The less viscous a substance, the lower the energy that is required to disperse a large bubble of the substance into small droplets. Silicone oil with a viscosity of 1000 mPas (a measurement of viscosity) is easier to inject and can be removed in less time than silicone oil with a viscosity of 5000 mPas, but the lower viscosity levels leads to earlier emulsification. With the advent of smaller gauge vitrectomies, there is a perceived need for less viscous silicone oil that can be introduced and removed more easily through smaller sclerotomies and finer instruments and cannulae. Therefore, there is a conflicting demand for the choice of silicone oil. The aim of this study is to investigate the natural course of silicone oil emusification between 2000-centistoke and 5000-centistoke SO.

Who can participate?
Adults aged 18 and older who have complicated vitreoretinal diseases.

What does the study involve?
Participants undergo the pars plana vitrectomy and SO tamponade. Participants are randomly

allocated to either receiving silicone oil with a viscosity of 2000 or receiving the silicone oil viscosity of 5000 centistokes. Participatns are followed up at one month, three months, six months and 12 months to measure their visual ability and intraocular pressure.

What are the possible benefits and risks of participating?
The patients can enjoy priority surgery and get subsidies for the trip. There is no risk for those participants taking part in the study except the risk of pars plana vitrectomy itself.

Where is the study run from?
Zhongshan Ophthalmic Center (China)

When is the study starting and how long is it expected to run for?
August 2014 to May 2017

Who is funding the study?
National Natural Science Foundation of China (China)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Institutional Review Board of Zhongshan Ophthalmic Center (2017KYPJ059)

Study information

Scientific Title
Analysis of the rate of emulsification in intraocular silicone oil tamponade of differing viscosity

Study objectives
The rate of emusification in silicone oil tamponade of different viscosity used in pars plana vitrectomy in the treatment of retinal detachment is different.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board of Zhongshan Ophthalmic Center, ref: 2017KYPJ059

Study design
Prospective cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Vitreoretinal cases that were considered to have a high risk of redetachment

Interventions
Patients who underwent pars plana vitrectomy and SO tamponade due to complicated vitreoretinal disease are included in the study. All procedures are performed by a single surgeon, using similar surgical procedures and techniques. Surgery involved a 23-gauge 3-port pars plana approach (Constellation® Vision System, Alcon Laboratories, Inc., Fort Worth, TX, USA), detachment of the posterior hyaloid face, vitrectomy, endolaser photocoagulation around the tears or peripheral retina, fluid-air exchange followed by air-silicone oil exchange. Silicone oil with viscosity of 2000 (Siluron 2000, Fluoron GmbH, Neu-Ulm, Germany) and 5000 (Siluron 5000) centistokes are used randomly in a 1:1 ratio according to the method of random number table. All cases are followed-up in the first postoperative day and 1 month, 3 month, 6 month and 12 months postoperatively. The eye examination included the measurement of best-corrected visual acuity, slit-lamp examination, intraocular pressure (IOP) measurement, dilated funduscopy.

Intervention Type
Device

Primary outcome measure
The rate of silicone oil emusification is measured using the slit lamp to observe the sign of silicone oil emulsification at 1 month, 3 months, 6 months and 12 months.

Secondary outcome measures
1. Retinal redetachment, is defined either as a complete retinal redetachment or if there was a progressive local retinal detachment that could not be confined by laser treatment at any time during the follow-up
2. Cataract progression is determined by one doctor if considered to be visually significant at 12 months
3. Corneal abnormalities measured using slitlamp as a bullous- or band-shaped keratopathy, epithelial- or stromal edema or localized opacities at 6 months and 12 months
4. Raised intraocular pressure (IOP) is measured using non-contact tonometer by IOP of more than 25 mmHg or more than 20 mmHg with antiglaucoma medication at any time during the follow-up
5. Hypotony is measured using non-contact tonometer as IOP of less than 5 mmHg at any time during the follow-up

Overall study start date
01/08/2014

Completion date
01/05/2017

Eligibility

Key inclusion criteria
1. The patients who underwent pars plana vitrectomy and SO tamponade due to complicated vitreoretinal diseases
2. Older than 18

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Key exclusion criteria

Cannot follow up.

Date of first enrolment
01/09/2014

Date of final enrolment
01/11/2016

Locations

Countries of recruitment
China

Study participating centre
Zhongshan Ophthalmic Center
No.54 Xianlie South Road
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Sponsor information

Organisation
Zhongshan Ophthalmic Center

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Sponsor type
Hospital/treatment centre

Website
http://www.gzzoc.com

ROR
https://ror.org/0064kty71

Funder(s)

Funder type
Not defined

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal. The additional documents (such as study protocol, statistical analysis plan, other) can be available.

Intention to publish date
01/09/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date