Safety and performance of silicone oil in retinal detachment surgery.

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The documentation of safety and performance of silicone oil as temporary tamponade in retinal surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON38831

Source
ToetsingOnline

Brief title
Endotamponades: silicone oil

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
retinal detachment

Research involving
Human

Sponsors and support

Primary sponsor: D.O.R.C. International BV
Source(s) of monetary or material Support: D.O.R.C. International BV, Scheijdelveweg 2, 3214 VN Zuidland,D.O.R.C. International BV;Scheijdelveweg 2;3214 VN Zuidland

Intervention

Keyword: compex retinal detachment, Intraocular pressure, pars plana vitrectomy, silicone oil tamponade

Outcome measures

Primary outcome

Intraocular pressure, macula attached.

Secondary outcome

Preoperatively:

Demographic characteristics: gender, age, ethnicity.

Preoperatively, at postop day 1 and 14 (± 3), and at week 26 (± 2):

Proportion of patients with IOP within 5-25 mm Hg.

Proportion of patients with retina attached.

Proportion of patients with macula attached.

Preoperatively, at week 6 (± 1), 26 (± 2) and 52 (± 4):

Visual acuity.

Peroperatively:

Diagnostic details, surgical procedure.

Intaoperative adverse events.

At any (other) postoperative visit:

Proportion of patients with IOP within 5-25 mm Hg.

Proportion of patients with retina attached.

Proportion of patients with macula attached.

Keratopathy.

Silicone oil emulsification.

Silicone oil in anterior chamber.

Date of silicone oil removal.

Additional surgery.

Glaucoma medication.

Intraocular inflammation.

Optic neuropathy or abnormalities of the retinal nerve fibre layer.

Cataract classification (LOCS).

Other postoperative adverse events/complications.

Study description

Background summary

Standard treatment for patients with complex retinal detachment (RD) involves pars plana vitrectomy in combination with silicone oil tamponade. With this study, we will be able to reliably evaluate the clinical outcomes of patients treated for complex RD.

Study objective

The documentation of safety and performance of silicone oil as temporary tamponade in retinal surgery.

Study design

Prospective observational.

Intervention

Intervention is identical to conventional intervention (sterilization is different).

Study burden and risks

Treatment of patients does not deviate from standard surgery. Measurements for the purpose of this study will include standard clinical assessments only.

Except two extra study visits (2 x 1.5 h), participation in this study does not involve any additional burden. The product to be used in this study, *Silicone Oil, 1.000-1.500 mPas, 10 ml syringe*, is identical to the product registered for the European market, with the exception of its sterilization procedure. This is not anticipated to affect the risk of adverse events.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

rhegmatogenous retinal detachment and giant tear,
rhegmatogenous retinal detachment and PVR,
diabetic tractional detachment with proliferative diabetic retinopathy.

Exclusion criteria

NA.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2014
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Silicone oil
Registration:	No

Ethics review

Approved WMO

Date:	09-12-2013
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	NL45732.078.13