

European multicentre randomised controlled clinical trial: Heavy Silicone Oil (HSO) versus standard silicone oil as long term vitreous tamponade

Submission date 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 20/12/2005	Overall study status Completed	☐ Protocol
Last Edited 14/07/2014	Condition category Eye Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
OZR-2004-06; NTR185

Study information

Scientific Title

Acronym

HSO-Study

Study objectives

Efficacies of heavy silicone oil and of standard silicone oil, as long-term vitreous tamponade in patients with complex ablatio retinae, are equivalent.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the local medical ethics committee before participants were recruited

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Retinal detachment, proliferative vitreoretinopathy

Interventions

Randomised to:

1. Heavy silicone oil, or
2. Standard silicone oil

As long-term vitreous tamponade.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Heavy silicone oil, standard silicone oil

Primary outcome(s)

Complete retinal reattachment and Early Treatment Diabetic Retinopathy Study (ETDRS) vision after 12 months.

Key secondary outcome(s)

Number of resurgeries within 12 months

Completion date

01/05/2007

Eligibility

Key inclusion criteria

1. Ablatio retinae with proliferative vitreoretinopathy (PVR)
2. Giant tear below 10 - 12 hours

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Defects above 10 - 12 hours
2. Proliferative diabetic retinopathy
3. Trauma
4. Uveitis
5. Glaucoma
6. Monoculus

Date of first enrolment

01/05/2005

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Oogziekenhuis Rotterdam

Rotterdam

Netherlands

3011 BH

Sponsor information

Organisation

Rotterdam Eye Hospital (Oogziekenhuis Rotterdam) (The Netherlands)

ROR

<https://ror.org/02hjc7j46>

Funder(s)

Funder type

Research organisation

Funder Name

Foundation of Scientific Research at the Eye Hospital (Stichting Wetenschappelijk Onderzoek het Oogziekenhuis) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration