The Vitreous Wipe. Clinical evaluation of an investigational medical device.

Published: 28-08-2018
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To establish the proportion of complete vitreoschisis removal with PVA.

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

Summary

ID

NL-OMON46076

Source
ToetsingOnline

Brief title
Vitreous wipe.

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
Retinal detachment (or other damage)

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Vooralsnog geen financiele ondersteuning;hoofdonderzoeker staat garant voor kosten.

Intervention

Keyword: Iatrogenic retinal damage, Polyvinyl alcohol, Vitrectomy, Vitreoschisis

Outcome measures

Primary outcome

Completeness of vitreoschisis removal, as visualised with triamcinolone,

intraoperatively.

Secondary outcome

Visual outcome, compications.

Study description

Background summary

Vitreoschisis causes retinal traction with a high risk of retinal damage. Therefore, it should be completely removed from the retinal surface. Existing equipment for vitreoschisis removal involve a substantial risk of iatrogenic retinal damage. It is conjectured that polyvinyl alcohol (PVA) comprises a safe and efficient alternative tool for removing vitreoschisis.

Study objective

To establish the proportion of complete vitreoschisis removal with PVA.

Study design

Prospective proof of concept (single-surgeon).

Intervention

Removing vitreoschisis with the Vitreous Wipe.

Study burden and risks

Unremoved vitreoschisis appears to be associated with retinal detachment after vitrectomy. Compared to existing instruments for vitreoschisis removal, the Vitreous Wipe is conjectured to reduce the risk of retinal (re-)detachment. No extra visits are required. Exclusively study related assessments will take approximately 3 hour extra time.

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

Informed consent. (If vitreoschisis is positively identified intraoperatively, subject agrees with the use of the Vitreous Wipe.)
Age * 18 years.

Exclusion criteria

Previous vitrectomy.
Tractional retinal detachment.
Proliferative retinal vascular disease.
Proliferative vitreoretinopathy.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-11-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-08-2018
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	NL65546.078.18