SLO-imaging for quantifying the efficacy of Nd:YAG-laser vitreolysis for disturbing vitreous floaters.

Published: 29-05-2015
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To determine the efficacy of quantification of vitreous floaters captured by SLO-imaging technique for Nd:YAG vitreolysis for persisting vitreous floaters.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Eye disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON42721

Source
ToetsingOnline

Brief title
Vitreous floaters & SLO-imaging

Condition

- Eye disorders NEC

Synonym
vitreous floaters

Research involving
Human

Sponsors and support

Primary sponsor: Oogziekenhuis Rotterdam
Source(s) of monetary or material Support: Stichting Wetenschappelijk Onderzoek Oogziekenhuis (SWOO)

Intervention

Keyword: ND: YAG vitreolysis, SLO-imaging, Vitreous floaters

Outcome measures

Primary outcome

Reduction of floater area measured on SLO-image at six months after first laser treatment.

Secondary outcome

Safety.

Number of treatments (1, 2 or 3).

Applied laser energy per treatment session.

Visual acuity (logMAR).

OCT: optic nerve and the macula (cystoid macular edema y/n).

Intraocular pressure.

Fundusphotograph.

Peripheral retinal exam.

Visual function questionnaire VFQ-25.

Floater questionnaire (see Appendix).

Study description

Background summary

Presently, pars plana vitrectomy (PPV) is the standard treatment for floaters causing serious complaints; patient satisfaction is high. However, many ophthalmologists are somewhat reluctant to operate on eyes with normal (or hardly reduced) VA due to the risk of complications. An alternative treatment, the Nd:YAG laser, has a better safety profile than PPV but appears to be only moderately efficacious. A generally accepted test to quantify complaints may

help to develop a preferred practice pattern for vitreous floaters.

Study objective

To determine the efficacy of quantification of vitreous floaters captured by SLO-imaging technique for Nd:YAG vitreolysis for persisting vitreous floaters.

Study design

Prospective, observational study.

Study burden and risks

Participants do not benefit. Risks are negligible; burden is minimal. Required extra time is maximally 2.5 hours.

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

Age >= 18 years.
Informed consent.
Floaters not adjacent to the lens or retina (> 2 mm).
Complaints lasting > 3 months.
Vitreous floaters are PVD related.

Exclusion criteria

History of glaucoma, uveitis, macular degeneration, retinal defect (eye to be treated or fellow-eye), macular edema, vascular retinal disease.
Other condition causing increased straylight, such as corneal haze, guttata, corneal surgery, refractive surgery, cataract affecting vision, PCO, contact lenses, iris diaphany, peripheral iridectomy/iridotomy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2016
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	29-05-2015
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	NL52882.078.15