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Effect of YAG Vitreolysis Laser treatment on vision-degrading vitreous floaters in short-sighted patients or patients with a posterior vitreous detachment

Submission date
15/06/2023

Recruitment status
No longer recruiting

Registration date
27/07/2023

Overall study status
Ongoing

Last Edited
22/01/2026

Condition category
Eye Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Floaters are small, semi-transparent specks or shapes that appear to float across a person's field of vision. They may look like dots, threads, or cobwebs and are most noticeable when looking at a bright background, such as a blue sky or a white wall. Floaters are actually tiny clumps of gel or cells that cast a shadow on the retina (the light-sensitive layer at the back of the eye), causing them to be visible. While they are generally harmless, floaters can sometimes be bothersome or interfere with clear vision.
The purpose of this study is to evaluate the efficacy and safety profile of a specific laser treatment to split floaters which are perceived by patients as bothersome into smaller pieces

Who can participate?
Anyone aged 18 years and above who is complaining of bothersome floaters in either one or both eyes. In the latter case, the retina specialist will determine which of the two eyes will be treated as part of this study.

What does this study involve?
An initial visit to The Retina Clinic London to determine suitability for this study by thoroughly screening the patient's eyes (baseline visit). If suitable, the patient will be offered laser treatment of his/her floaters in one eye. After treatment, the patient will be asked to come back to The Retina Clinic London for follow-up visits including the same testing regimen as at the baseline visit, at months 3, 6 and 12.

What are the possible benefits and risks of participating?
The possible benefits for the patients who suffer from bothersome floaters in their vitreous to improve visual function, quality of life and mental health.
Possible risks: We expect any risk to the patient's eye to be negligible. To avoid collateral damage, eyes will only be included in this study where the posterior vitreous interface is shown to be a minimum of 3mm from the retinal surface as measured by ultrasound and/or OCT, and

where the posterior vitreous is 6mm from the lens (1.5 lens thickness) anterior to which no floaters will be treated. The surgeon will employ a pulse offset of 300 microns (which delivers the actual laser shockwave either behind, or in front of the focusing target, depending on the setting) to further amplify this safety zone: anteriorly offset (i.e. in front of the focusing target) for floaters located anterior to the mid vitreous and posterior offset (i.e. behind the focusing target) for floaters located posterior to the mid vitreous. There will be no offset used for floaters in the mid vitreous. Energy used will range between 1.5 and 5.0 mJ per single pulse with a recommended maximum total energy dose of 1,600 mJ applied per session. Energy of 5.0 mJ is only to be used when treating floaters in the mid vitreous and lower settings should be used closer to the retina or the lens.

Where is the study run from?
The Retina Clinic London (UK)

When is the study starting and how long is it expected to run for?
January 2023 to January 2027

Who is funding the study?
The Retina Clinic London (UK)

Who is the main contact?
Dr Paulo E Stanga, p.stanga@theretinacliniclondon.com

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Integrated Research Application System (IRAS)
324015

Protocol serial number
TRCL001

Study information

Scientific Title
Effect of YAG laser vitreolysis on vitreous structure and visual function in patients with vision degrading myodesopsia secondary to myopic vitreopathy or posterior vitreous detachment

Acronym
YVL Laser Study

Study objectives
The aim of the study is to determine the safety and efficacy of Nd:YAG laser treatments for VDM in eyes with vitreous opacities due to MV and PVD. It is hypothesised that there will be a positive correlation between changes in objective measures of vitreous opacities and functional outcomes pre- and post- laser. It is further hypothesised that patients suffering from VDM may have improvements in visual function as well as quality-of-life after laser treatment(s) that correspond to a quantitative decrease in the size and/or number of vitreous opacities post-treatment. Lastly, it is hypothesised that Nd:YAG laser vitreolysis will be more effective in eyes with PVD than in eyes with MV.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/04/2023, West Midlands - Edgbaston Research Ethics Committee (3rd Floor Barlow House, Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 2071048089; edgbaston.rec@hra.nhs.uk), ref: 23/WM/0077

Primary study design
Interventional

Study design
Single-arm non-randomized prospective pre- and post-interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of floaters in the vitreous in patients with bothersome symptoms

Interventions
Only patients with bothersome floaters will be recruited for this study. They will undergo the following testing regimen:
1. Visual Function testing using the ETDRS eye charts: Visual Acuity logMAR Best-Corrected Visual Acuity (BCVA) and Low Luminance Best-Corrected Visual Acuity (LL-BCVA).
2. Reading function assessment using the hand-held MNREAD chart.
3. Visual Function Questionnaire using the 39-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25 + Optional Items).
4. VFFQ (Vitreous Floaters Functional Questionnaire).
5. High-Definition Analyser (HDA)
6. Light Distortion Analyser (LDA)
7. C-Quant
8. Contrast Sensitivity Function test using the Freiburg Acuity Contrast Test (FrACT).
9. Ultrasonography (ABSolu 20MHz annular array).
10. Electroretinography (ERG) using the RETeval® Hand-Held, Full-Field ERG.
11. Optos Multiwavelength and Autofluorescence Ultra widefield Imaging: Central with Steering.
12. Widefield spectral domain optical coherence tomography scan (WF SD-OCT) centered on the fovea.
13. Slit lamp Biomicroscopy.
14. Microperimetry.
15. Indirect Ophthalmoscopy with 360-degree scleral indentation.

Eyes will only be included in this study where the posterior vitreous interface is shown to be a minimum of 3 mm from the retinal surface as measured on ultrasound and/or OCT, and where the posterior vitreous is 6 mm from the lens (1.5 lens thickness) anterior to which no floaters will be treated.
Before the procedure, the pupil is dilated with 1% Tropicamide and 2.5% Phenylephrine and the surface of the eye is anesthetised using 0.4% Oxybuprocaine Hydrochloride. Then, the contact lens is placed on the eye. Under direct observation with a slit lamp biomicroscope using coaxial illumination, the laser is brought to focus upon the opacities in the vitreous body. Opacities to

be treated are selected with a minimum distance of 3 mm from the retina and 6 mm from the lens to safeguard against untoward effects upon the lens anteriorly and the retina and optic disc posteriorly.
The surgeon will employ a pulse offset of 300 microns to further amplify this safety zone: anteriorly offset for floaters located anterior to the mid vitreous and posterior offset for floaters located posterior to the mid vitreous. There will be no offset used for floaters in the mid vitreous.
Nanosecond pulses of laser with minimum levels of energy will be applied and increased as needed to achieve photo disruption of vitreous opacities. Energy used will range between 1.5 and 5.0 mJ per single pulse with a recommended maximum total energy dose of 1,600 mJ applied in a session.
Energy of 5.0 mJ is only to be used when treating floaters in the mid vitreous and lower settings should be used closer to the retina or the lens.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Floater location, density, and acoustic scatter measured using quantitative ultrasound imaging, before and after YAG laser vitreolysis

Key secondary outcome(s)
Measured at baseline, 3 months, 6 months, 12 months:
1. Visual Acuity (ETDRS LogMAR)
2. Near Visual Acuity
3. Visual Function Questionnaire (VFQ-25)
4. Vitreous Floater Functional Questionnaire (VFFQ)
5. Contrast Sensitivity Function (CSF)
6. Quantitative Ultrasonography (B-Scan)
7. Electroretinography (ERG)
8. Optos Multiwavelength and Autofluorescence Ultrawidefield Imaging
9. Optical Coherence Tomography (OCT)
10. Microperimetry (MP)
11. Indirect Ophthalmoscopy with 360 Degree Scleral Indentation
12. High Definition Analyser (HDA)
13. Light Distortion Analyser (LDA)
14. C-Quant

Completion date
05/01/2027

Eligibility

Key inclusion criteria
1. Able and willing to give informed consent.
2. Age ≥18 years
3. Suffering from symptomatic vitreous floaters visible on contact lens biomicroscopy in one or both eyes.
4. Floaters arising from either/both:
4.1. Myopic vitreopathy
4.2. Posterior vitreous detachment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Present with vitreous opacities outside of the described safety area described in section 3.1.1 (i.e., 3 mm vicinity of the retina and 6 mm vicinity of the lens).
2. Visually significant cataract that either causes sufficient media opacity to reduce quality of imaging or would require surgery during the study follow up period.
3. High risk of peripheral lesions requiring treatment at the discretion of the local PI during the study period (if patients require and receive treatment for these at screening, they may be rescreened after 2 months following procedure, at the discretion of the PI).
4. Vitreous floaters or PVD symptoms present for less than three months.
5. Unable to attend study appointments.
6. Synchysis scintillans.
7. Asteroid hyalosis.
8. Vitreous haemorrhage.
9. Active photopsia.
10. Active uveitis.
11. Active proliferative diabetic retinopathy, and/or other significant retinal vascular pathology
12. Pre-existing visual field loss (including uncontrolled glaucoma).
13. Inherited retinal diseases.
14. History of, or active ocular trauma/penetrating ocular injury.
15. Any significant vitreoretinopathy e.g., current or previous retinal detachment, epiretinal membrane, macular hole.
16. History of previous YAG laser vitreolysis treatments, or previous vitreoretinal surgery for any condition (such as retinal detachment, proliferative diabetic retinopathy).
17. History of complicated cataract surgery (e.g anterior vitrectomy).
18. History of intraocular surgery within 6 months from starting the study.
19. Any other significant ocular or non-ocular condition that, at the discretion of the local PI, puts the subject at risk or influences the results of the study.

20. Patients who, in the opinion of the investigator, would be unwilling or unable to provide written informed consent, or undergo the testing procedures as described in the protocol.
21. Pregnant or breastfeeding women

Date of first enrolment
05/05/2023

Date of final enrolment
01/01/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Retina Clinic London
24 Queen Anne Street
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Sponsor information

Organisation
The Retina Clinic London

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	version 1.4	02/05/2023	03/07/2023	No	Yes