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Study evaluating the safety and efficacy of YAG laser for the treatment of vitreous opacity

Submission date
29/09/2022

Recruitment status
No longer recruiting

Registration date
13/10/2022

Overall study status
Completed

Last Edited
14/11/2022

Condition category
Eye Diseases

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

Plain English summary of protocol

Background and study aims
Dots and lines (floaters) or flashes of light in your vision are common. They're usually caused by a harmless process called posterior vitreous detachment (PVD), where the gel inside your eyes changes. Symptomatic vitreous opacities are floaters that are bothersome enough to motivate a patient to seek relief. Symptomatic vitreous floaters significantly and negatively impact quality of life.
Recently Ultra Q Reflex™ neodymium-doped yttrium-aluminum-garnet (YAG) laser vitreolysis is a popular treatment. The objective of this study was to evaluate the efficacy and safety of YAG laser vitreolysis in the treatment of vitreous floaters.

Who can participate?
Patients with symptoms of floaters from a posterior vitreous detachment (PVD).

What does the study involve?
Patients were randomly divided into 2 groups by a random number. Number 1 referred to treatment group, Number 2 referred to un-treatment group (only observation). Patients in treatment group will be installed eye drops for surface anesthesia and pupil dilation before laser treatment. No eye drops will be administered after the laser treatment. A contact lens with eye moisturizer will be used on the surface of the treatment eye to perform the YAG vitreolysis. The number of shots will be determined at the discretion of the treating physician. Single shot mode will be used. The maximum energy per pulse will be 7 mJ. The endpoint of treatment is the disruption of the vitreous opacities into smaller fragments as well as any other vitreous opacities deemed visually significant by the treating physician. Only one treatment session will be performed. Patients will have intraocular pressure checked before and 30 minutes after procedure.

What are the possible benefits and risks of participating?
It is understood that participation in this study may not derive any direct medical benefits to patients. Patients may have a good response to treatment; however, it is possible that patients may not see an improvement. Information from your participation in this study may benefit persons with symptomatic floaters from posterior vitreous detachment Weiss ring in the future. The risks of YAG laser treatment that occur in about 1 in every 100 patients are an increased eye

pressure, glaucoma and cataract formation. Risks that occur in about 1 in every 1000 patients are eye inflammation, retinal tear, retinal detachment, retinal edema, and optic nerve injury. The minor side effects include conjunctival hemorrhage (bleeding outside the eye), eye redness and irritation, headache, or new floaters.

Where is the study run from?
Aier Eye Hospital Group (China)

When is the study starting and how long is it expected to run for?
February 2019 to March 2022

Who is funding the study?
Science Research Foundation of Aier Eye Hospital Group, China (AM1901D1).

Who is the main contact?
Jiannan Liu, lomicheal@163.com

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
HEBAIER201904

Study information

Scientific Title
Efficacy and safety of YAG laser vitreolysis for symptomatic posterior vitreous detachment

Acronym
ESYLV

Study objectives

AG laser vitreolysis is effective and safe for symptomatic posterior vitreous detachment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/02/2019, Harbin Aier Eye Hospital (509 Haoyao Street, Harbin, China; +86 045188810988; 39166163@qq.com), ref: HEBAIER2019IRB06

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of symptomatic posterior vitreous detachment via YAG laser vitreolysis.

Interventions
Randomization was achieved by employing a random number for each patient, 1 for treatment and 2 for control. Patients in treatment group will be dilated with phenylephrine 2.5% and tropicamide 1% and proparacaine prior to YAG laser. No postoperative eye drops will be administered. A Karickoff lens with goniosol will be used to perform the YAG vitreolysis. The number of shots will be determined at the discretion of the treating physician. Single shot mode will be used. The maximum energy per pulse will be 7 mJ. The endpoint of treatment is the disruption of the Weiss ring into smaller fragments as well as any other vitreous opacities deemed visually significant by the treating physician. Only one treatment session will be performed. Patients will have intraocular pressure checked by applanation onometry before and 30 minutes post-procedure.

Intervention Type
Procedure/Surgery

Primary outcome(s)
At preoperative, postoperative week 1, month 1, month 3 and month 6:
1. Visual disturbance measured using a 10-point visual disturbance score (with 0 being asymptomatic and 10 indicating impairing symptoms)
2. Degree of patients disturbed by floaters measured using a short questionnaire of 4-degree floater symptoms
3. Symptoms improvement percentage measured using a 4-level qualitative scale

Key secondary outcome(s)
At preoperative, postoperative week 1, month 1, month 3 and month 6:
1. The National Eye Institute Visual Functioning Questionnaire 25 (NEI VFQ-25)
2. Best corrected visual acuity (BCVA)

Completion date
31/03/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 14/11/2022:

1. Symptomatic vitreous opacities owing to complete PVD (Weiss ring), symptoms for at least 3 months
2. No sensation of flashing for at least 2 weeks
3. Clear optical media
4. The distance between floaters and retina or lens was over 3mm (measured by B-scan ultrasound)
5. The 10-point visual disturbance score of at least 4
6. Ability to undertake YAG laser procedure
7. Acceptance of related risks

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Previous inclusion criteria:

1. Symptomatic vitreous opacities owing to complete PVD (Weiss ring), symptoms for at least 3 months
2. Clear optical media
3. The distance between floaters and retina or lens was over 3mm (measured by B-scan ultrasound)
4. The 10-point visual disturbance score at least 4
5. Ability to undertake YAG laser procedure
6. Acceptance of related risks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
306

Key exclusion criteria
Current exclusion criteria as of 11/11/2022:

1. Snellen BCVA was worse than 20/50
2. Patients with a history of glaucoma, severe cataract, vitreous hemorrhage, retinal disease, macular disease.

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Previous exclusion criteria as of 18/10/2022:

1. Snellen BCVA was worse than 20/50
2. Less than 50% of the Weiss ring was ablated after one treatment (objective changes were evaluated by the surgeon who performed the YAG laser vitreolysis); patients with a history of glaucoma, severe cataract, vitreous hemorrhage, retinal disease, macular disease.

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Previous exclusion criteria:

1. Snellen BCVA was worse than 20/50
2. Eyes with intraocular lens (IOL)
3. Less than 50% of the Weiss ring was ablated after one treatment (objective changes were evaluated by the surgeon who performed the YAG laser vitreolysis); patients with a history of glaucoma, severe cataract, vitreous hemorrhage, retinal disease, macular disease.

Date of first enrolment
08/10/2019

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
China

Study participating centre
Harbin Aier Eye Hospital
NO.509 Hayao Road
Harbin
China
150076

Sponsor information

Organisation
Harbin Aier Eye Hospital

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Aier Eye Hospital Group

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file			12/10/2022	No	No