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Evaluating very low-level red light therapy for dry age-related macular degeneration

Submission date	Recruitment status	[_] Prospectively registered
21/09/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/09/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/09/2026	Eye Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Scientific, Public

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Additional identifiers

Study information

Scientific Title
Six-month multicenter clinical study evaluating the safety and efficacy of low fluence photobiomodulation using a wearable multi-wavelength visible light device in nonexudative age-related macular degeneration

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2022, Low Vision Academy Scientific Ethics Committee (Piazza Sempione 3, Milano, 20145, Italy; +39 (0)23315865; a.manassero@fgeditore.it), ref: 2022/C930

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Nonexudative age-related macular degeneration (dry AMD)

Interventions
Patients were randomized (approximate 2:1 allocation ratio) using a computer-generated permuted block sequence (Research Randomizer). Randomisation was performed strictly at the

patient level (both eyes of a participant received the same assignment). Allocation concealment and blinding were managed by an independent, unblinded study coordinator who generated the allocation sequence, scheduled participants, and distributed physically identical devices. Participants and data analysts remained strictly blinded throughout the study (single-blind trial).

Active treatment arm:
Participants received photobiomodulation (PBM) therapy using a wearable, frame-based low-level red light device (incorporating non-coaxial LEDs at 605 nm, 630 nm, and 660 nm with zero blue light emission). The treatment regimen consisted of:
1. Induction phase: 10 sessions (12 minutes each) over 15 days
2. Maintenance phase: three sessions per week (12 minutes each) for 6 months
3. Setting: performed in outpatient clinic settings under medical/healthcare supervision

Sham control arm:
Participants underwent an identical treatment schedule (10 induction sessions over 15 days, followed by three weekly sessions for 6 months) using a physically identical device that provided no active PBM therapy.

Treatment duration: 6 months.

Follow-up evaluations: baseline, 1 month and 6 months. Assessments included BCVA (ETDRS), microperimetry (macular integrity assessment [MAIA] for macular response stability and full threshold), optical coherence tomography macular thickness, intraocular pressure, and a patient-reported usability/comfort questionnaire.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Jupiter TM

Primary outcome(s)
1. Retinal sensitivity measured using fundus-controlled microperimetry at baseline , 1 month and 6 months

2. Visual acuity measured using BCVA at 40 cm an 4 m expressed in logMAR and converted to ETDRS letters at baseline and after 8 months

Key secondary outcome(s)

Completion date
20/03/2025

Eligibility

Key inclusion criteria
1.Age ≥50 years
2. Early, intermediate and late dry AMD (AREDS1)

3. Best corrected visual acuity (BCVA) 50–75 ETDRS letters
4. Microperimetry sensitivity 5–25 dB
5. Ability to comply with home treatment
6. Written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
50 Years

Upper age limit
101 Years

Sex
All

Total final enrolment
45

Key exclusion criteria
1. Neovascular AMD
2. Significant media opacities (cataract, posterior capsule opacification)
3. Recent ocular surgery
4. Glaucoma with field loss
5. Diabetic macular edema
6. Uveitis or photosensitivity
7. Severe systemic disease
8. Participation in another trial within 3 months

Date of first enrolment
08/01/2023

Date of final enrolment
29/09/2024

Locations

Countries of recruitment
Italy

Sponsor information

Organisation
Low Vision Academy

Funder(s)

Funder type

Funder Name
Low Vision Academy

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available