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Neuroregenerative effects of transorbital extremely low-frequency low-amplitude pulsed electromagnetic therapy in retinal vein occlusion

Submission date
21/03/2026

Recruitment status
Recruiting

Registration date
25/03/2026

Overall study status
Ongoing

Last Edited
25/03/2026

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
Plain English summary of protocol not provided at time of registration

Contact information

Type(s)
Scientific, Public, Principal investigator

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Study information

Scientific Title

Neuroregenerative effects of transorbital extremely low-frequency low-amplitude pulsed electromagnetic therapy in non-ischemic branch retinal vein occlusion

Acronym
Trabsorbital ELF-LA-PEMT for RVO

Study objectives
The purpose of this study is to evaluate the efficacy of transorbital ELF-LA-PEMT combined with intravitreal ranibizumab for the management of Retinal Vein Occlusion (RVO). The study analyzes longitudinal changes in central retinal thickness (CRT), total macular volume (TMV), and best-corrected visual acuity (BCVA) immediately post-treatment and at a three-month follow-up.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/03/2025, Ethic Comittee of Medical Dental Institute (Pskovskaya, 9, Moscow, 127253, Russian Federation; +7 (499) 5045476; medinstmcu@inbox.tu), ref: 185

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Basic science, Device feasibility, Diagnostic, Health services research, Prevention, Screening, Supportive care, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Confirmed diagnosis of macular edema secondary to branch retinal vein occlusion or central retinal vein occlusion.

Interventions
This research is a two-arm, longitudinal, prospective analysis of patients with non-ischemic superior temporal RVO.
Randomization was generated using IBM SPSS Statistics software (version 20). Patients in the intervention group received a course of transorbital ELF-LA-PEMT using a contact ophthalmic emitter applied to the closed affected eye while in a supine position. The therapy involved a continuous, clockwise running magnetic field with an induction of 6 mT and a frequency of 12

Hz. Treatment sessions lasted 20 minutes and were administered on alternate days for a total of 15 sessions. The TMT procedures were initiated one month after the first ranibizumab injection and were carried out over one month. Procedures were conducted using the POLIMAG-02 magnetotherapeutic complex (Elamed, Russia), a specialized system for low-frequency, low-intensity pulsed electromagnetic field (PEMF) therapy. The device (Registration No. RZN 2017 /6315, dated October 3, 2017) is manufactured in the Ryazan region, Russia. The control group received anti-VEGF monotherapy only.

Central retinal thickness (CRT) and total macular volume (TMV) were measured using optical coherence tomography (OCT) at baseline, as well as at the first and third months post-treatment. BCVA and visual evoked potential (VEP) tests were evaluated at the same intervals.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
POLIMAG-02 magnetotherapeutic complex

Primary outcome(s)
1. Regenerative and recovery effects, via assessments of central retinal thickness, total macular volume, best corrected visual acuity (BCVA), and visual evoked potentials measured using optical coherence tomography (OCT), BCVA and visual evoked potential (VEP) tests at before treatment, after treatment, and at the end of the third month of follow-up

Key secondary outcome(s)
1. Well-being, activity, and mood quality of life of patients after RVO measured using 36-Item Short Form Survey (SF-36) and SAN (translated from the Russian САН: Самочувствие, Активность, Настроение) questionnaires at before treatment, after treatment, and at the end of the third month of follow-up

Completion date
01/06/2031

Eligibility

Key inclusion criteria
1. European
2. Men and women from 40 to 70 years old
3. Non-ischemic rvo of the superior temporal branch of the central retinal vein
4. Recent onset of retinal vein thrombosis ≤15 days
5. Central retinal thickness: between 350 μm and 600 μm
6. Total macular volume: between 9 mm^3 and 15 mm^3

Healthy volunteers allowed
No

Age group

Mixed

Lower age limit
40 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
200

Key exclusion criteria
1. Presence of acute inflammatory diseases of the eye or systemic infections
2. Exudative retinal detachment
3. Poor response to the first anti-vegf injection (decreae of central retinal thickness < 20%)
4. Paroxysmal and mental disorders
5. Systemic thrombophilic disorders
6. Exacerbation of comorbid conditions during the study period
7. Intercurrent illness during the course of treatment
8. History of previously administered antiangiogenic therapy for the current condition
9. Failure to meet follow-up requirements
10. Presence or possibility of pregnancy
11. Decompensation of hypertension and diabetes mellitus
12. History of stroke or multiple sclerosis

Date of first enrolment
19/03/2025

Date of final enrolment
19/03/2031

Locations

Countries of recruitment
Russian Federation

Sponsor information

Organisation
Peoples' Friendship University of Russia

ROR
https://ror.org/02dn9h927

Funder(s)

Funder type

Funder Name
RUDN University

Alternative Name(s)
Российский университет дружбы народов, Rossiysky universitet druzhby narodov, Université RUDN, Universidad de Rusia de la Amistad de los Pueblos, , , Peoples' Friendship University of Russia

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Russian Federation

Funder Name
Medical Dental Institute, Russia

Funder Name
I.M. Sechenov First Moscow State Medical University

Alternative Name(s)
Moscow State Medical University, Sechenov University, MSMU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Russian Federation

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available