

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of adjuvant intraoperative intravitreal triamcinolone on the optical coherence tomography-wise macular anatomy following vitrectomy for epiretinal membrane: a Randomized clinical trial

Protocol summary

Study aim

To evaluate the Effect of intravitreal triamcinolone during vitrectomy with epiretinal membrane peeling on the macular Optical coherent tomography characteristics.

Design

This is a prospective randomized controlled study of patients with idiopathic epiretinal membrane (ERM). Patients will be randomized in to two groups. Best corrected visual acuity (BCVA), Slit-lamp biomicroscopy, OCT and intraocular pressure (IOP) were measured for all patients before operation and 1, 3, 6 and 12 months after operation. The patients' BCVAs will be converted to a logarithm of the minimal angle of resolution (logMAR) scale for analysis. A p-value <0.05 is considered to be significant.

Settings and conduct

pars plana vitrectomy and membrane peeling will be done in operation room in shiraz at khalili Hospital

Participants/Inclusion and exclusion criteria

women and men that have age between 50 to 80 years with following inclusion criteria: • Patients with idiopathic epiretinal membrane (ERM), Decreased vision(BCVA:20/400-20/40) or meta-morphopsia and central foveal thickness more than 320 micron. Exclusion criteria; • Previous retinal surgery, • retinal detachment, • Age related macular degeneration, • diabetic retinopathy, • retinal vascular occlusion, • uveitis, • vitreous hemorrhage, • trauma, • ocular tumors, • glaucoma, • optic atrophy, • fibrotic epiretinal membrane, • macular pathologies other than ERM, • significant cataract • corneal opacity • incomplete chart records

Intervention groups

Group1(N=20) included patients who underwent pars plana vitrectomy and membrane peeling without IVTA. Group 2 (N=20) included patients who underwent pars plana vitrectomy , membrane peeling and 1 mg

intravitreal triamcinolone injection during operation.

Main outcome variables

central subfield thickness, best corrected visual acuity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201120049450N4**

Registration date: **2024-04-12, 1403/01/24**

Registration timing: **retrospective**

Last update: **2024-04-12, 1403/01/24**

Update count: **0**

Registration date

2024-04-12, 1403/01/24

Registrant information

Name

Ehsan Namvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 4088

Email address

namvar_e@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-11, 1402/09/20

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adjuvant intraoperative intravitreal triamcinolone on the optical coherence tomography-wise macular anatomy following vitrectomy for epiretinal membrane: a Randomized clinical trial

Public title

Effect of intravitreal triamcinolone injection on macular anatomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with idiopathic epiretinal membrane (ERM)
Decreased vision(BCVA:20/400-20/40) or metamorphopsia Central foveal thickness more than 320 micron

Exclusion criteria:

Previous retinal surgery, retinal detachment, Age related macular degeneration, diabetic retinopathy, retinal vascular occlusion, uveitis vitreous hemorrhage, trauma ocular tumors, glaucoma optic atrophy, fibrotic epiretinal membrane, macular pathologies other than ERM, significant cataract corneal opacity incomplete chart records.

Age

From **50 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Method will be used to generate the random allocation sequence is block randomization (A: intervention group & B: control group □ blocks: AABB, ABBA, BABA,BBAA, BAAB, ABAB); By using free online random sequence generator (www.sealedenvelope.com) block randomization was done with quaternary blocks. Random allocation sequencing was done by statistics specialist.

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, Outcome assessors and data analyzer will be blinded to groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Khalili street

City

shiraz

Province

Fars

Postal code

7193636981

Approval date

2021-10-11, 1400/07/19

Ethics committee reference number

IR.SUMS.REC.1400.551

Health conditions studied**1****Description of health condition studied**

Epiretinal membrane

ICD-10 code

H35.379

ICD-10 code description

Puckering of macula, unspecified eye

Primary outcomes**1****Description**

central subfield thickness

Timepoint

before operation and 1, 3, 6 and 12 months after operation

Method of measurement

macular OCT

2**Description**

best corrected visual acuity

Timepoint

before operation and 1, 3, 6 and 12 months after operation

Method of measurement

snellen chart

Secondary outcomes

1

Description

retinal sublayers

Timepoint

before operation and 1, 3, 6 and 12 months after operation

Method of measurement

optical coherence tomography

2

Description

intraocular pressure

Timepoint

before operation and 1, 3, 6 and 12 months after operation

Method of measurement

Tonometry

Intervention groups

1

Description

Intervention group: patients with idiopathic ERM who underwent pars plana vitrectomy and membrane peeling with intravitreal injection of triamcinolone acetonide (IVTA).

Category

Treatment - Surgery

2

Description

Control group: patients with idiopathic ERM who underwent pars plana vitrectomy and membrane peeling without intravitreal injection of triamcinolone acetonide (IVTA).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili hospital

Full name of responsible person

Ehsan namvar

Street address

Khalili street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ehsan Namvar

Position

assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only are to be shared

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

available for people working in academic institutions

Under which criteria data/document could be used

meta-analysis or references

From where data/document is obtainable

namvar.e@gmail.com

What processes are involved for a request to access data/document

email

Comments