# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

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Iran (Islamic Republic of)

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**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 triamsinolone 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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Namvar.e@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Ehsan Namvar
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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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## Person responsible for updating data

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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**