Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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)

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+98 71 3627 4088

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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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
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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