

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Survey the effect of intra-silicon oil Triamcinolone acetonide on macular anatomy after vitrectomy for rhegmatogenous retinal detachment

Protocol summary

Study aim

Determination of effect of intra-silicon oil Triamcinolone acetonide injection after vitrectomy in patients with rhegmatogenous retinal detachment on reduction of retinal atrophy Determination of effect of intra-silicon oil Triamcinolone acetonide injection after vitrectomy in patients with rhegmatogenous retinal detachment on reduction of second retinal detachment Determination of effect of intra-silicon oil Triamcinolone acetonide injection after vitrectomy in patients with rhegmatogenous retinal detachment on best corrected visual acuity improvement

Design

Randomized control trial, two arm parallel group randomized trial with double blinded outcome assessment. Randomization was done with concealed blocked randomization chart.

Settings and conduct

The patients participated in investigation, will be evaluated before operation, 1, 3 and 6 months after operation by best corrected visual acuity, IOP and macula OCT. Except investigator, no one is aware of specified codes and its meanings.

Participants/Inclusion and exclusion criteria

Including criteria: age more than 18 year old, rhegmatogenous retinal detachment including macula which lasts about 1 month since initial symptoms
Excluding criteria: aphakia, pseudophakia with previous complicated cataract surgery, previous retinal surgery, diabetic retinopathy, axial length more than 26 mm and less than 20 mm, need to retinotomy, abnormal optic disk, glaucoma or IOP more than 21 mm Hg before operation, abnormal retina, tractional retinal detachment, vitreous hemorrhage, history of anti-VEGF injection, post operative complications

Intervention groups

In intervention group, at the end of vitrectomy and silicon oil injection operation, Triamcinolone acetonide by dose of 1 mg/0.05 cc will be injected.

Main outcome variables

Evaluation about effect on retinal atrophy, retinal second detachment and best corrected visual acuity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200620047837N1**

Registration date: **2020-08-08, 1399/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-08, 1399/05/18**

Update count: **0**

Registration date

2020-08-08, 1399/05/18

Registrant information

Name

Mohammad Hossein Nowroozzadeh

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3629 1779

Email address

nowroozzadeh@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-27, 1399/04/07

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of intra-silicon oil Triamcinolone acetonide on macular anatomy after vitrectomy for rhegmatogenous retinal detachment

Public title

Effect of Intra-silicon oil Triamcinolone acetonide on macular anatomy in rhegmatogenous retinal detachment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age more than 18 year old Rhegmatogenous retinal detachment involving macula Need for vitrectomy surgery and silicon oil injection Less than 1month since symptoms initiation

Exclusion criteria:

Aphakia Pseudophakia with previous complicated cataract surgery Any complication during previous ocular surgeries Previous scleral buckling surgery, pneumatic surgery and vitrectomy surgery Diabetic retinopathy Axial length more than 26 mm or less than 20 mm Abnormal optic disk Need to retinotomy History of uveitis Glucoma or IOP more than 21 mm Hg before operation Abnormal retina such as coloboma and choroidal detachment Tractional retinal detachment Vitreous hemorrhage History of anti-VEGF injection

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by blocked method. 6 persons will place in every block equally. Randomization chart will be used as randomization tool.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants don't have any information about the group they participate in. No information will be registered on operation note and follow up note about injection of Triamcinolone acetonide in both groups. Every patient will be known by a special code witch only the investigator knows that code belongs to which group. Also analyzer and evaluator of consequences are

unaware about codes and their specification to every group.

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

Shiraz university of Medical Sciences central building, Zand Blvd, shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2020-02-22, 1398/12/03

Ethics committee reference number

IR.SUMS.MED.REC.1398.644

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

Rhegmatogenous retinal detachment

ICD-10 code

H33.0

ICD-10 code description

Retinal detachment with retinal break

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

Macular thickness

Timepoint

Before operatio; 1, 3 and 6 months after operation

Method of measurement

Macular OCT with Heidelberg

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 1 time Triamcinolone acetonide within sclerotmy site by dose of 1 mg/0.05 cc from 40mg ampoule made by Alborz Darou company at end of vitrectomy and silicon oil injection operation

Category

Treatment - Drugs

2

Description

Control group:Triamcinolone acetonide is not injected. Other procedures are identical to intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili hospital

Full name of responsible person

Mohammad hosein Nowroozzadeh

Street address

Khalil hospital, Khilil Ave., Mollasadra street, Shiraz

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Nowroozzadeh@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ghasemi, Y. Pharm.D, PhD

Street address

Shiraz University of Medical Sciences central building, Zand Blvd, Shiraz

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Email

Vcrdep@sums.ac.ir

Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor of 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

Mohammad hosein Nowroozzadeh, MD

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Due to all gathered data from patients evaluate unknownly, all these informations are sharable totally.

When the data will become available and for how long

6 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

Evaluation of survey and gathering data method

From where data/document is obtainable

Email to Nowroozzadeh@hotmail.com Refer or contact to Poostchi ophthalmology research center dependent on Shiraz university of medical sciences, phone number: 0098 7132302830, Fax: 0098 7132355936

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

At first contact to Nowroozzadeh@hotmail.com and send your request; then contact to Poostchi ophthalmology research center dependent on Shiraz university of medical sciences, phone number: 0098 7132302830, Fax: 0098 7132355936

Comments