

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Possible effect of statin use on the occurrence of retinal detachment secondary to PVR in patients with a history of successful vitrectomy or scleral buckling surgery referred to Rassoul Akram Ophthalmology Clinic, Randomized Clinical Trial

Protocol summary

Study aim

statin could reduce the incidence of secondary retinal detachment in patients with a history of successful vitrectomy or scleral buckle

Design

pilot RCT, 2 arm parallel-group, triple blinded, 3rd phase, single center

Settings and conduct

110 patients (divided into 2 groups; 1, treatment group, using Atorvastatin 40mg for 3 months and 2, control group, using a placebo for 3 months). patients will be visited at 1 day, 1 week and 1, 3 and 6 months after the surgery. all patient's data will be recorded completely. the lab test will be done for each patient.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age>40 primary attachment following PPV with silicone oil or sf6 tamponade vs scleral buckle regular follow up all of the surgery was done with a single surgeon in a single center exclusion criteria: 1.combined RD 2.recurrent RD 3.RRD associated with a giant tear 4.Secondary RD due to other than PVR 5.intraoperative complications like vitreous or suprachoroidal hemorrhages 6.concomitant eye diseases affecting the retina including glaucoma, CSR, acquired and congenital retinal dystrophies, etc. 7.PVRc 8.lactation and pregnancy 9.systemic steroid use 10.Taking different medications that can interfere with statin use

Intervention groups

110 patients (divided into 2 groups; 1, treatment group, using Atorvastatin 40mg for 3 months and 2, control group, using a placebo for 3 months). Atorvastatin is made with Actover company

Main outcome variables

retinal redetachment secondary to PVR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191207045645N1**

Registration date: **2020-06-08, 1399/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-08, 1399/03/19**

Update count: **0**

Registration date

2020-06-08, 1399/03/19

Registrant information

Name

Fatemeh Abdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8826 2137

Email address

abdi.fa@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-16, 1398/09/25

Expected recruitment end date

2021-12-16, 1400/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Possible effect of statin use on the occurrence of retinal detachment secondary to PVR in patients with a history of successful vitrectomy or scleral buckling surgery referred to Rassoul Akram Ophthalmology Clinic, Randomized Clinical Trial

Public title

statin in PVR related redetachment

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

age>40 primary attachment following PPV with silicon oil or sf6 tamponade vs scleral buckle regular follow up all of the surgery was done with a single experienced surgeon in a single center

Exclusion criteria:

combined RD recurrent RD RRD associated with giant tear Secondary RD due to other than PVR intraoperative complications like vitreous or suprachoroidal hemorrhages Other concomitant eye diseases affecting the retina including glaucoma, CSR, acquired and congenital retinal dystrophies, etc. PVRc lactation and pregnancy systemic steroid use Taking different medications that can interfere with statin use

Age

From **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

online randomization system (<https://www.randomization.com>) block randomization block size: 4 with 1 by 1 proportion

Blinding (investigator's opinion)

Triple blinded

Blinding description

The study participants were not aware of the intervention type because the main drug and placebo were not distinguishable. The principal investigator who evaluates the outcome is also unaware of the type of intervention because the medication is prescribed by another person performing the randomization. The analyzer is also supposed to analyze the data as two groups a and b, the type of intervention is unknown.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Iran university of medical science

Street address

Iran university of medical science, Hemmat highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-12-16, 1398/09/25

Ethics committee reference number

IR.IUMS.REC.1398.980

Health conditions studied

1

Description of health condition studied

secondary retinal detachment

ICD-10 code

H33.0

ICD-10 code description

Retinal detachment with retinal break

Primary outcomes

1

Description

secondary retinal detachment

Timepoint

1 day, 1 week and 1,3 and 6 months after the surgery

Method of measurement

examinations and OCT imaging

Secondary outcomes

1

Description

comparing the rate of retinal detachment in groups of using statin and using placebo

Timepoint

day 1, week 1, month 1,3 and 6

Method of measurement

slit lamp examination and OCT

Intervention groups**1****Description**

Intervention Group: Use of Atorvastatin 40 mg (Actover Pharmaceutical Company) daily for 3 months after successful vitrectomy or scleral buckling surgery for retinal detachment.

Category

Treatment - Drugs

2**Description**

Control group: Use of placebo (Actover Pharmaceutical Company) daily for 3 months after successful vitrectomy or scleral buckling surgery for retinal detachment.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat e rasool e akram hospital

Full name of responsible person

Fatemeh Abdi

Street address

Sattarkhan

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Postal code

1445613131

Phone

+98 21 6435 2473

Fax**Email**

iumseyeddept@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Iran University of Medical Sciences

Full name of responsible person

Abbas Motevalian

Street address

Hemmat Highway next to Milad Tower, Iran 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

Vice Chancellor for Research, Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Abdi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Hazrat e Raool Akram hospital, Sattarkhan

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Abdi

Position

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Latest degree

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Other areas of specialty/work

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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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

clinical data and examination without any clue of patients identifications are available

When the data will become available and for how long

after registry of all date (2 months after the last examination)

To whom data/document is available

all staff related to the university

Under which criteria data/document could be used

clinical data and examination and analysis results without any clue of patients identifications are available

From where data/document is obtainable

Fateme Abdi

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

A written request will be received by Dr. Fatemeh Abdi and regarding the request, the time of publishment will be announced

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

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Abdi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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