Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Phacoemulsification + IOL Implantation and Silicone Oil Removal in One Session with Performing These Operations in Two Sessions

Protocol summary

Study aim

Comparison of one-step Fico surgery, intraocular lens implantation and silicone oil discharge with two-step silicone oil discharge procedure

Design

In the first group, discharge of silicone oil is performed through Pars Planana sclerotomy. In the second group, discharge of silicone oil is done by posterior capsular rex or Pars Plana sclerotomy. Silicone oil drainage surgery is performed at least 3 months after vitrectomy and silicone injection with complete retinal adhesion. Cataract surgery is performed when progressive lens opacity has reduced visual acuity in periodic examinations. To calculate the intraocular lens power in the presence of silicone oil, the ratio of sound velocity in silicon oil (986 m / s) to velocity in vitro (1555 m / s) is used. Lens power is determined by the IOL Master.

Settings and conduct

This prospective and non-randomized study was performed in Imam Khomeini Hospital in Ahvaz in 2018-2019. Cataract surgery is performed with two approaches of superior or temporal incision followed by capsulorrhexis, followed by hydroduction, intra-capsular phacoemulsification and cortical material removal, viscoelastic gel injection, anterior chamber and capsular ligation, and capsular ligation.

Participants/Inclusion and exclusion criteria

All patients with cataract diagnosis after vitrectomy and injection of silicone oil that require cataract surgery and discharge of silicone oil are included in this study. Patients who did not return for follow-up or had other major ophthalmic surgeries with this type of surgery were excluded from the present study.

Intervention groups

The first group undergoes surgery in two stages. Silicone oil drainage surgery followed by cataract surgery in two stages. The second group undergoes cataract surgery and silicone oil drainage in one phase.

Main outcome variables

Improve vision, benefits and complications of one-stage and two-stage surgery

General information

Reason for update

Acronym

COTP

IRCT registration information

IRCT registration number: **IRCT20191221045841N1**
Registration date: **2020-10-04, 1399/07/13**
Registration timing: **retrospective**

Last update: **2020-10-04, 1399/07/13**
Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

feraidoon farahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 8076

Email address

farahi-f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-20, 1397/12/29

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date
2019-03-20, 1397/12/29
Actual recruitment end date
2019-09-21, 1398/06/30
Trial completion date
2019-09-21, 1398/06/30

Scientific title
Comparison of Phacoemulsification + IOL Implantation and Silicone Oil Removal in One Session with Performing These Operations in Two Sessions

Public title
Comparison of One Session and Two Sessions of Phacoemulsification
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
This study is non-randomized in Imam Khomeini Hospital in Ahvaz at 2019-2020. Patients with a diagnosis of cataract after vitrectomy and silicone oil injection into the study.
Exclusion criteria:
Patients who did not return for follow-up. major ophthalmic surgeries with this type of surgery were excluded.
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **25**
Actual sample size reached: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are divided into two groups based on the Four Random block permutation method.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Patients with cataract after vitrectomy and injection of silicone oil that require vitrectomy and discharge of silicone oil are divided into two groups at a specified interval.The first group undergoes surgery in two stages. Silicone oil drainage surgery followed by cataract surgery in two stages.The second group will undergo a single cataract surgery and discharge of silicone oil.In the first group, discharge of silicone oil is performed through Pars Planana sclerotomy. In the second group, discharge of silicone oil is done by posterior capsular rex or Pars Plana sclerotomy.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahwaz Jundishapour University of Medical Sciences
Street address
Imam Khomeini Street - Imam Khomeini Hospital
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2019-05-03, 1398/02/13
Ethics committee reference number
IR.AJUMS.REC.1398.130

Health conditions studied

1

Description of health condition studied
One-stage and two-stage Phaco surgery
ICD-10 code
H52.7
ICD-10 code description
Unspecified disorder of refraction

Primary outcomes

1

Description
Refraction
Timepoint
one week, one month, three month, six month
Method of measurement
autorefractometer

Secondary outcomes

1

Description
UCVA and BCVA
Timepoint
one week, one month, three month, six month
Method of measurement
autorefractometer

Intervention groups

1

Description
Intervention group: One-step - In this method, silicone oil is drained, cataract surgery and intraocular lens implantation are performed in one step. The equipment required in this method includes vitrectome device, vitrectome probe, fibropeptic light probe, Phaco device, silicone oil and intraocular lens.

Category
Treatment - Surgery

2

Description
Intervention group: Two Sessions- In this method, first the silicone oil is drained in one step and then the lens is inserted in the next step. The equipment required in this method includes vitrectome device, vitrectome probe, fibropeptic light probe, Phaco device, silicone oil and intraocular lens.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Khomaini Hospital

Full name of responsible person
Feraidoon Farrahi

Street address
Azadegan St

City
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6193673111

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Fax

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feraidoonfarrahi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Mohammad Diyanat

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Habib.kakaei67@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Feraidoon Farrahi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Feraidoon Farrahi

Position
Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Habibollah Kakaei

Position

Resident

Latest degree

Medical doctor

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information on sample collection and analysis

When the data will become available and for how long

One years

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Similar studies

From where data/document is obtainable

Correspond Author

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

By Email

Comments