

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Efficacy of Combined Internal Limiting Membrane Peeling and Macular Detachment surgery compared to Internal Limiting Membrane Peeling and Flap surgery in the treatment of Large macular hole in Isfahan city in 2023

Protocol summary

Study aim

Determining the effectiveness of macular detachment surgery compared to internal limiting membrane peeling and flap surgery in the treatment of large macular hole

Design

A clinical trial with a control group, parallel groups, double-blind, randomized based on the software of Dr. Saqai, will be conducted on 30 patients.

Settings and conduct

After obtaining the approval of the university ethics committee and obtaining a written consent form the patients, they enter the study. Before surgery, the best visual acuity of all patients is measured using the Snellen chart and calculated as LogMAR. Macula imaging is performed on all patients with the help of SD-OCT device. In MH imaging, its size is based on the minimum width of the macular hole that is measured by the device and recorded in the file. With the help of Dr. Saghaee's software, randomization is done and the surgeon is obliged to perform one of the two surgical methods based on randomization. 1. Combined MD and ILM peeling surgical method or 2. ILM peeling and inverted flap surgical method. Surgeries will performed in Feiz Hospital, Isfahan. After 3 months, the visual acuity, the rate of successful closure of the macular hole, will be compared between two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Macular hole greater than 400 microns based on clinical examination and SD-OCT 2. Macular hole that the patient's symptoms have lasted for less than 2 years 3. Age over 50 years Exclusion criteria: History of any retinal surgery or retinal laser

Intervention groups

1.combined MD and ILM peeling 2. Internal limiting membrane (ILM) peeling and inverted flap

Main outcome variables

The successful rate of anatomical closure of the macular hole and its effect on improving visual acuity in each of the two surgical methods

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230226057539N1**

Registration date: **2023-05-20, 1402/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-20, 1402/02/30**

Update count: **0**

Registration date

2023-05-20, 1402/02/30

Registrant information

Name

Khodayar Golabchigilani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-10, 1401/12/19

Expected recruitment end date

2023-06-09, 1402/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Combined Internal Limiting Membrane Peeling and Macular Detachment surgery compared to Internal Limiting Membrane Peeling and Flap surgery in the treatment of Large macular hole in Isfahan city in 2023

Public title

Comparison of macular detachment surgery with ILM flap in retinal hole treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Macular hole greater than 400 microns based on clinical examination and Spectral Domain Optical Coherence Tomography (SD-OCT) Macular hole (MH) in which the patient's symptoms have lasted less than 2 years Age above 50 years

Exclusion criteria:

Perform any retinal surgery or retinal laser Retinal holes due to secondary causes such as trauma Stage 1 or 2 macular holes Any disease other than Macular Hole (MH) that affects visual acuity except cataract If, for any reason, silicone oil is injected for tamponade during surgery

Age

From **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the method of random allocation (randomization software of Dr. Soqaei), the patients were divided into two groups of 15 patients using the first surgical method, macular detachment (MD) or the second surgical method (Internal limiting membrane peeling with inverted flap). By ensuring the randomness of the treatment allocation, this software reduces the interactive effect of unknown factors and helps to examine the effect of the treatment more accurately. First, we enter the details of the plan include the number of groups (2 groups), the number of participants in each group (15 patients) and the type of the treatment (first or second surgical method) into the software. Then, using the random assignment option, numeric and

random codes are given in the software, and the software randomly divides the patients into the first or second surgical groups, and the surgeon selects the surgical method using the obtained information. The software link is below:

<https://drive.google.com/file/d/0B9juB1UY-iu4TzZUVzZLOVZvM0k/view?usp=sharing>

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be informed about the two surgical procedures, but will not be informed about which surgical procedure will be used for them. Based on randomization with the help of the software, the surgeon will be obliged to perform the surgery for the patient based on the scientific principles of surgery without having the right to choose the surgical method for the patient. Finally, the examination will be continued by the researcher.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

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MUI, Hezarjarib St

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Isfahan

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8114673461

Approval date

2023-01-23, 1401/11/03

Ethics committee reference number

IR.MUI.MED.REC.1401.377

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

Macular hole

ICD-10 code

H35.34

ICD-10 code description

Macular cyst, hole, or pseudohole

Primary outcomes

1

Description

What is the success rate of closing the anatomical macular hole (MH) with macular detachment (MD) based on Spectral domain Optical Coherence Tomography (SD-OCT)?

Timepoint

Before surgery and 1 and 3 months after surgery

Method of measurement

The degree of success in the anatomical closure of the macular hole is expressed by SD-OCT analysis.

2

Description

What is the success rate of anatomical closure of MH with Inverted Flap Of Internal Limiting Membrane Peeling (i-ILM peeling) based on SD-OCT?

Timepoint

Before surgery and 1 and 3 months after surgery

Method of measurement

The degree of success in the anatomical closure of the macular hole is expressed by SD-OCT analysis.

3

Description

What is the level of visual acuity before and after MH surgery using the MD method with the help of Snellen chart and in the form of Logarithm of Minimum Angle of Resolution (LogMAR)?

Timepoint

Before surgery and 1 and 3 months after surgery

Method of measurement

Visual acuity is measured with the help of Snellen chart and is expressed based on Logarithm of Minimum Angle of Resolution (LogMAR).

4

Description

What is the level of visual acuity before and after MH surgery using the i-ILM peeling method with the help of Snellen chart and LogMAR?

Timepoint

Before surgery and 1 and 3 months after surgery

Method of measurement

Visual acuity is measured with the help of Snellen chart and is expressed based on Logarithm of Minimum Angle of Resolution (LogMAR).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: combined Macular detachment and Internal Limiting Membrane peeling surgery 1. Deep

vitrectomy is performed in the standard way with 3 ports.2. If the posterior hyaloid is not detached, posterior vitreous detachment is induced.3. ILM staining is done with the help of Brilliant Blue, and after 1 to 2 minutes, ILM peeling is done in the macular area in a circular manner in the vascular area.4. BSS injection is done through a 25/38 gauge cannula which is connected to a syringe containing BSS. These injections are done in 4 quadrants. The injection continues until the retinal bleb reaches the edge of the macular hole and can be seen exiting through the hole.5. Finally, air-fluid exchange is performed and internal tamponade is performed with the help of undiluted C3F8 gas in the amount of 0.4 ml inside the vitreous, and the patient is asked to sleep with face down position.

Category

Treatment - Surgery

2

Description

Control group: Internal Limiting Membrane peeling and inverted flap . 1. Deep vitrectomy is performed.2. ILM staining is performed, ILM peeling is performed in the macular area in a circular manner in the vascular area.3. The removed ILM is placed as a flap inside the macular hole.4. Finally, air-fluid exchange is performed and internal tamponade is performed with the help of undiluted C3F8 gas, and the patient is asked to lie with face down position.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz Hospital

Full name of responsible person

Khodayar Golabchi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Khodayar Golabchigilani

Position

Fellowship resident

Latest degree

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Only part of the data related to the main outcome will be shared.

When the data will become available and for how long

Access will start after the completion of the study and at the time of submitting the study to scientific journals.

To whom data/document is available

Only researchers working in academic and scientific institutions

Under which criteria data/document could be used

Data analysis will be possible only after obtaining permission from the authors and researchers.

From where data/document is obtainable

Responsible author or scientific responsible for the study with the help of the email

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

After requesting the data, the researchers will work together to send the data information to the requester within one month.

Comments