# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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**

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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**
Isafahan University of Medical Sciences
**Street address**
MUI, Hezarjarib St
**City**
Esfahan
**Province**
Isfehan
**Postal code**
۸۱۷۴۶۷۳۴۶۱
**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
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## Sponsors / Funding sources

**1**

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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**
Specialist
**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**
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**