

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 2026

### comparison between retinal injury and success in treatment of macular hole surgery (pinch versus scraper)

#### Protocol summary

##### Study aim

comparison between retinal injury and success in treatment of macular hole closure with two different methods for ILM peeling (pinch versus scraper)

##### Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

##### Settings and conduct

All patients with stage 2 and more of macular hole that were candidates for surgery and went to Khatamanbia Hospital were chosen and then in a randomised method were split into interventional and control groups. In the control group, the same surgical method for macular hole surgery for ILM peeling used a pinch instrument and the interventional group for ILM removal used a diamond dusted membrane scraper. Another surgical method was the same in both groups. These two instruments were the same in both groups. The macroscopic morphological appearance of the patient, researcher, and analyzer did not have any information about the type of group.

##### Participants/Inclusion and exclusion criteria

**Inclusion criteria:** All patients with macular hole stage 2 and more that were candidates for surgical treatment of macular hole closure. **Exclusion criteria:** Diabetic retinopathy, AMD, retinal occluded vessel disease, myopic patient, history of ocular inflammatory disease, trauma, lamellar macular hole, chronic macular hole (more than 12 months), previous ILM peeling surgery, previous vitrectomy.

##### Intervention groups

**Interventional group:** We used a diamond dusted membrane scraper with the same macroscopic morphological appearance. **Control group:** We used a pinch for ILM removal at the same time in both groups had vitrectomy and gas injection (with the same surgical method).

##### Main outcome variables

the rate of success for macular hole closure

#### General information

##### Reason for update

##### Acronym

scraper in macular hole surgery

##### IRCT registration information

IRCT registration number: **IRCT20180406039202N1**

Registration date: **2019-04-16, 1398/01/27**

Registration timing: **retrospective**

Last update: **2019-04-16, 1398/01/27**

Update count: **0**

##### Registration date

2019-04-16, 1398/01/27

##### Registrant information

##### Name

yalda jannesar boroujerdi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3768 0933

##### Email address

jannesary941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-22, 1396/10/01

##### Expected recruitment end date

2018-11-06, 1397/08/15

##### Actual recruitment start date

2018-02-12, 1396/11/23

##### Actual recruitment end date

2019-01-29, 1397/11/09

##### Trial completion date

2019-01-29, 1397/11/09

## Scientific title

comparison between retinal ingery and success in treatment of macular hole surgery(pinch versus scraper)

## Public title

comparison between retinal ingery and success in treatment of macular hole surgery(pinch versus scraper)

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

any patient with stage 2 and more of macular hole that candidatet for surgery.

### Exclusion criteria:

Diabetic retinopathy AMD Retinal occuded vessel Myopic patients, History of ocular inflamatory disease trauma Lamelar macular hole Chronic macular hole (more than 12 months) Previous ILM peeling Previous vitrectomy

## Age

From **50 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

## Sample size

Target sample size: **20**

Actual sample size reached: **20**

## Randomization (investigator's opinion)

Randomized

## Randomization description

simple randomization,individual,pinch( control group ) versus scraper (intreventional group)instrument.patient,researcher and analyser did not have any information about type of groups.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

we used pinch instrument in control group hower we used scraper in interventional group(its appearance is looks like pinch .but it had diamond-dusted membrane scraper and under surgical microscope .it could be difference) for ILM peeling .patients.researcher, analayzer.did not have any information about type of group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of mashhad university of medical scienses

##### Street address

Mashad university of medical sciense, azadi ave,mashad

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

#### Approval date

2018-01-03, 1396/10/13

#### Ethics committee reference number

IR.MUMS.fm.REC.1396.646

## Health conditions studied

### 1

#### Description of health condition studied

Macular hole

#### ICD-10 code

H35.89

#### ICD-10 code description

Other specified retinal disorders

## Primary outcomes

### 1

#### Description

anatomic success of macular hole closure

#### Timepoint

in comparison between retinal ingery and anaomic success in macular hole closure in 2 different method of ILM peeling with pinch versus scraper, the anatomic success checked 3 months after surgery with OCT

#### Method of measurement

in comparison between retinal ingery and anaomic success in macular hole closure in 2 different method of ILM peeling with pinch versus scraper, the anatomic success checked 3 months after surgery with OCT(optical coherense tomography)

## Secondary outcomes

### 1

#### Description

Visual acuity

#### Timepoint

before and 3 months after surgery

#### Method of measurement

Visual acuity measurment by snellen chart

2

**Description**

Macular thickness and density

**Timepoint**

before and 3 months after surgery

**Method of measurement**

OCT-A instrument

3

**Description**

RNFL thickness

**Timepoint**

before and 3 months after surgery

**Method of measurement**

RNFL-OCT instrument

**Intervention groups**

1

**Description**

Intervention group: use Diamond -dusted membrane scraper for ILM peeling with vitrectomy and gas injection

**Category**

Treatment - Surgery

2

**Description**

Control group: In this group we used the same surgical Macular hole procedure technique for ILM peeling .at the same time we used vitrectomy and Gas injection

**Category**

Treatment - Surgery

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Khatamanbia hospital in mashhad

**Full name of responsible person**

Shoeybi Naser

**Street address**

Khatamambia hospital, abootaleb ave, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9195965919

**Phone**

+98 51 3728 9911

**Email**

Shoeybin@mums.ac.ir

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeid Eslami

**Street address**

ghoreyshi building, daneshgah ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9195965919

**Phone**

+98 51 3845 2474

**Email**

ramresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Shoeybi Naser

**Position**

associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Ophthalmology

**Street address**

Khatam alanbia hospital, abootaeb blvd, mashhad

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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**

Undecided - It is not yet known if there will be 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**

any detail going to published

**When the data will become available and for how long**

6 months after validity

**To whom data/document is available**

Any scientific and collegiate institutions

**Under which criteria data/document could be used**

Any analysis allowed

**From where data/document is obtainable**

Yaldajannesar@gmail.com

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

About 1 month after request with email

**Comments**