

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

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Mashhad

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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

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9195965919

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+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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

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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

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