

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of subthreshold diode laser micropulse therapy versus conventional photocoagulation laser therapy as primary treatment of diabetic macular edema in the years of 2015-2016 at the Isfahan Feiz hospital

Protocol summary

Summary

Diabetic macular edema with foveal involvement is the most common cause of decrease vision in diabetic retinopathy patients. Diabetic macular edema is a resistance situation that completely resolving of the edema is nearly impossible. Nowadays conventional laser photocoagulation is the gold standard treatment but it accompany with retinal image because of continuous laser use. In attention to probable complications of laser photocoagulation newer methods with lesser damage were developed such as intra vitreal injection of anti-vascular endothelial growth factors and or steroids. Although these injections have had favorable results but they have their complications. For the best result of therapy, it needs to inject intra vitreal frequently, so it has the greater chance of complication and also greater cost. Subthreshold diode micropulse laser is a newer method in treatment of diabetic macular edema but the effect of this method in relation to old conventional laser photocoagulation needs more studies. We aimed in this randomized clinical trial to survey the effect of the subthreshold diode micropulse laser in comparison with the conventional laser photocoagulation in treatment of diabetic macular edema.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122721890N2**
Registration date: **2016-01-25, 1394/11/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-25, 1394/11/05

Registrant information

Name

Khodayar Golabchi

Name of organization / entity

Isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5533 1151

Email address

kh_golabchi@edc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of subthreshold diode laser micropulse therapy versus conventional photocoagulation laser therapy as primary treatment of diabetic macular edema in the years of 2015-2016 at the Isfahan Feiz hospital

Public title

The effect of the laser photocoagulation method in

treatment of diabetic macular edema

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: at least best corrected vision 20/200 or 1.00 LogMAR; the best corrected vision less than 20/25 or 0.10 LogMAR; diabetic macular edema with at least central macular thickness of 300 microns Exclusion criteria: monocular patients; diabetic macular edema with central macular thickness more than 450 microns; pregnant patients; uncontrolled diabetes mellitus defined with fasting blood glucose (FBS) more than 300 mg/dl and or Hb A1c[≥]10 mg/dl; uncontrolled hypertension defined with systolic blood pressure SBP more than 160 mmHg and or diastolic blood pressure (DBP) more than 110 mmHg; any history of intra orbital surgery except uncomplicated cataract surgery with phacoemulsification method; any history of previously intra ocular injection; any history of previously conventional laser photocoagulation of retina or subthreshold diode micropulse laser; previously history of glaucoma or ocular hypertension; macular diseases like vitreo macular traction(VMT), Epi retinal Membrane (ERM), Age related macular degeneration (AMD), proliferative diabetic retinopathy (PDR); extensive non capillary perfusion in fundus angiography of macula; pregnancy during the study; any visible scar in ophthalmic examination or fundus angiography during the study in group that treated with subthreshold diode micropulse laser; not follow up of patients; no acceptance to perform study.

Age
From **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

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

Street address

Isfahan University of Medical Sciences, Hezar Jarib Street

City

Isfahan

Postal code

Approval date

2015-11-11, 1394/08/20

Ethics committee reference number

IR.MUI.REC.1394.3.629

Health conditions studied

1

Description of health condition studied

diabetic macular edema

ICD-10 code

H36.0

ICD-10 code description

Diabetic retinopathy (E10-E14 with common fourth character .3+)

Primary outcomes

1

Description

Best corrected visual acuity

Timepoint

0, ,2, 4 Months

Method of measurement

With Snellen chart and then converted to LogMAR

2

Description

The mean of central macular thickness

Timepoint

0, ,2, 4 Months

Method of measurement

With optical coherence tomography (OCT) imaging technique (Microns)

3

Description

The mean of central macular volume

Timepoint

0, ,2, 4 Months

Method of measurement

With optical coherence tomography (OCT) imaging technique (Microns)

Secondary outcomes

1

Description

Complications of the conventional laser photocoagulation

Timepoint

2, 4 Months

Method of measurement

Fundus examination and fluorescein angiography

2**Description**

Complications of the subthreshold diode micropulse laser

Timepoint

2, 4 Months

Method of measurement

Fundus examination and fluorescein angiography

Intervention groups**1****Description**

After getting informed consent we will be studied 68 eyes that randomly will divide in two groups. First group will be get subthreshold diode micropulse laser photocoagulation (Quantel-medical Co, USA) as described below: adjustable power that begins of 1000 millivolt with duration time of 300 microseconds, 15 % of duty cycle and 75 to 125 microns spot size. All areas of thickened and edematous retina will be treated with distance of 100 microns of the FAZ in this method.

Category

Treatment - Devices

2**Description**

Conventional laser photocoagulation (Quantel-medical Co, USA) will be performed via dilated pupil in eyes of second group as described below: adjustable power with 50 to 100 microns spot size, 0.1 second duration time. Focal laser will be applied in distance of 500 to 3000 microns of the foveal avascular zone (FAZ) and also on microvascular lesions of the exudative ring, also grid laser will be applied on thickened retinal areas in 500 microns distance of the FAZ and 500 microns distance of temporal ridge of optic disc.

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Feiz Eye Center Hospital

Full name of responsible person**Street address****City**

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mahdi Nematbakhsh

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Majid Bagheri

Position

MD, Ophthalmology resident

Other areas of specialty/work**Street address**

Feiz Eye Center hospital, Modaress Street, Ghods Square, Isfahan

City

Isfahan

Postal code**Phone**

+98 31 3445 2033

Fax**Email**

bagheri.majid0612@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Farhad Fazel

Position

Associated professor

Other areas of specialty/work

Street address

Feiz Eye Center Hospital, Ghods Square, Isfahan

City

Isfahan

Postal code

Phone

+98 31 3445 2033

Fax

Email

fazel@med.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Khodayar Golabchi

Position

MD, Ophthalmology resident

Other areas of specialty/work

Street address

Feiz Eye Center Hospita, Ghods Sq., Isfahan

City

Isfahan

Postal code

Phone

+98 31 3445 2033

Fax

Email

kh_golabchi@edc.mui.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty