Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Isfahan university of medical sciences
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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.
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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
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
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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