

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the effect of Panretinal photocoagulation (PRP) versus PRP plus Intravitreal Bevacizumab on Macular Thickness, Macular Choroidal Thickness, Peripapillary Nerve Fiber Layer thickness by Optical Coherence Tomography in patients with diabetic retinopathy.

Protocol summary

Summary

This study is a single- blind randomized clinical trial which has been designed to determine the best treatment plan for diabetic retinopathy according to Macular Thickness, Macular Choroidal Thickness and Peripapillary RNFL Thickness. Patients with type 1 or 2 diabetes with Severe Nonproliferative diabetic retinopathy or Proliferative diabetic retinopathy in both eyes who have been referred to Farabi eye hospital retina clinic will be included. The exclusion criteria may include any type of previous retinal treatment and other retinal or optic nerve disease. The target sample size is 42 eyes in each group (according to a pilot study that has been done). Each eye will undergo SD-OCT then Panretinal Photocoagulation (PRP) will be done at 3 sessions. After first PRP, one intravitreal injection of 1.25 mg of Bevacizumab will be performed randomly in one of the each patient' eye. The patients will be followed with best corrected visual acuity (BCVA) and OCT at months 1, 3 and 6. Additional PRP in control group and intravitreal injection of 1.25 mg of Bevacizumab in treatment group will be performed if retreatment is needed at months 3 and 6. Macular Photocoagulation will be performed at first visit, months 3 and 6 if patients have clinically significant macular edema (either treatment or control group).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030116782N1**
Registration date: **2014-12-22, 1393/10/01**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

Name

Ramak Roohipoor

Name of organization / entity

Farabi Eye Research Center

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Sciences, Farabi Hospital, Ophthalmic Research Center

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Panretinal photocoagulation (PRP) versus PRP plus Intravitreal Bevacizumab on Macular Thickness, Macular Choroidal Thickness, Peripapillary Nerve Fiber Layer thickness by Optical

Coherence Tomography in patients with diabetic retinopathy.

Public title

The effect of laser on eye in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of severe Nonproliferative diabetic retinopathy or Proliferative diabetic retinopathy in both eyes; Normal intraocular pressure; Refractive error within ± 3 diopter (D). Exclusion criteria: Any type of previous retinal treatment (macular or peripheral laser photocoagulation, vitrectomy, intravitreal steroids and/or antiangiogenic drugs); Glaucoma or ocular hypertension; Significant media opacities that precluded fundus examination or imaging; Other retinal or optic nerve disease; Uncontrolled systemic hypertension (BP \geq 180/110); Central macular thickness \geq 350

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 42

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**

Tehran University Of Medical Sciences

Street address

Ghods Street, Enghelab Square

City

Tehran

Postal code**Approval date**

2014-10-23, 1393/08/01

Ethics committee reference number

0928 /پ م

Health conditions studied**1****Description of health condition studied**

Diabetic retinopathy

ICD-10 code

H36.0

ICD-10 code description

Diabetic retinopathy

Primary outcomes**1****Description**

macular thickness

Timepoint

before intervention, 1, 3 and 6 months after intervention

Method of measurement

Spectral domain optical coherence tomography (SD_OCT)

2**Description**

macular choroidal thickness

Timepoint

before intervention, 1, 3 and 6 months after intervention

Method of measurement

Spectral domain optical coherence tomography (SD_OCT)

3**Description**

peripapillary nerve fiber layer thickness

Timepoint

before intervention, 1, 3 and 6 months after intervention

Method of measurement

Spectral domain optical coherence tomography (SD_OCT)

Secondary outcomes**1****Description**

Best Corrected Visual Acuity (BCVA)

Timepoint

before intervention, 6 month after intervention

Method of measurement

Snellen acuity chart

2**Description**

total number of laser burns

Timepoint

after any PRP session

Method of measurement

by laser setting

Intervention groups

1

Description

Control group(PRP): PRP treatment by an argon green laser with a retinal spot size of 500 µm and moderate intensity(until a hazy, mucoid and translucent choroidal lesion become evident), the duration of the 0.2 second and the total number of spots 1200- 1600, at 3 sessions; Additional PRP at 3 and 6 months, if retreatment is needed; Macular Photocoagulation(MPC)at first visit or 3 and 6 months, if patients have clinically significant macular edema(CSME).

Category

Treatment - Other

2

Description

Treatment group(PRP plus IVB): PRP treatment by an argon green laser with a retinal spot size of 500 µm and moderate intensity(until a hazy, mucoid and translucent choroidal lesion become evident), the duration of the 0.2 second and the total number of spots 1200- 1600, at 3 sessions; One intravitreal injection of 1.25 mg of Bevacizumab in one of the patients' eyes randomly, 120 min after completion of the first PRP session; Intravitreal injection of 1.25 mg of Bevacizumab, at 3 and 6 months, if retreatment is needed; Macular Photocoagulation(MPC)at first visit or 3 and 6 months, if patients have clinically significant macular edema(CSME).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Eye Hospital

Full name of responsible person

Dr.Fariba Ghasemi

Street address

Southern Kargar Street, Qazvin Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University Of Medical Sciences, Farabi Hospital, Ophthalmic Research Center

Full name of responsible person

Dr. Mohammad Riazi

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Farabi Eye Hospital, Southern Kargar Street, Qazvin

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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

Tehran University Of Medical Sciences, Farabi Hospital, Ophthalmic Research Center

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

Farabi Hospital, Ophthalmic Research Center

Full name of responsible person

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Position

Associate Professor Of Ophthalmology

Other areas of specialty/work

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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