

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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)

###### **Phone**

+98 21 5542 1001

###### **Email address**

roohipoor@sina.tums.ac.ir

##### **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  $\pm 3$  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

##### Street address

Farabi Eye Hospital, Southern Kargar Street, Qazvin

Square

##### City

Tehran

##### 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

Dr. Ramak Roohipoor

##### Position

Associate Professor Of Ophthalmology

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Ophthalmic Research Center, Farabi Eye Hospital

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Elahe Sharifian

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Resident Of Ophthalmology

**Other areas of specialty/work**

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Farabi Eye Hospital, Southern Kargar Street, Qazvin  
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**Postal code**

1336616351

## 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*