Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ±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 hypertenion (BP ≥ 180/110); Central macular thickness ≥ 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
م پ/ 0928

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 tomograghy (SD_OCT)

2

Description
macular choroidal thickness
Timepoint
before intervention, 1, 3 and 6 months after intervention
Method of measurement
Spectral domain optical coherence tomograghy (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 tomograghy (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 Opthalmology
Other areas of specialty/work
Street address
Farabi Eye Hospital, Southern Kargar Street, Qazvin Square
City
Tehran
Postal code
Phone
+98 21 5541 6134
Fax
Email
roohipoor@sina.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Farabi Hospital, Ophthalmic Research Center
Full name of responsible person
Dr. Ramak Roohipoor
Position
Associate Professor Of Opthalmology
Other areas of specialty/work
Street address
Farabi Eye Hospital, Southern Kargar Street, Qazvin Square
City
Tehran

Postal code
Phone
+98 21 5541 6134
Fax
Email
roohipoor@sina.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ophthalmic Research Center, Farabi Eye Hospital
Full name of responsible person
Elahe Sharifian
Position
Resident Of Ophthalmology
Other areas of specialty/work
Street address
Farabi Eye Hospital, Southern Kargar Street, Qazvin Square
City
Tehran
Postal code
1336616351
Phone
+98 21 5541 6134
Fax
+98 21 5540 9095
Email
elahesharif425@yahoo.com
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