

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Intravitreal Bevacizumab alone or in combination with 1 mg Triamcinolone in diabetic macular edema

Protocol summary

Summary

Diabetic retinopathy is the main sight threatening disease in the developed world. Further, it is an increasing cause of blindness in developing countries. The goal of this study is to introduce safer and more effective treatment that can reduce the number of injections. This study will be conducted on 50 patients with bilateral diabetic macular edema in non-proliferative phase that have no previous medical or surgical treatment for it and will be visited in retinal clinic of Farabi eye hospital from October 2013 till June 2014. Each eye of a 50 patients will be randomly allocated to 2 different groups: IVB group, eyes receiving IVB injection alone; IVB/IVT group, eyes receiving IVB injection plus IVT. Before treatment complete ocular examination (include visual acuity), optical coherence tomography (OCT) and fluorescein angiography (FA) will be done. Each patient will be followed up for about 2 years. Complete ocular examination including Intraocular pressure, visual acuity and cataract progression estimation and also OCT will be done at follow ups sessions (2week, 4 week, 6 week, 8 week, 12 week, 6 month, 12 month and 24 month after treatments) . Finally two groups will be compared based on different visual acuity improvement, central macular reduction, cataract formation and intraocular pressure elevation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080818733N1**
Registration date: **2015-03-16, 1393/12/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-16, 1393/12/25

Registrant information

Name

Hamid Riazi Esfahani

Name of organization / entity

Farabi Eye hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2255 5790

Email address

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research- Tehran University of Medical Science

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-05-17, 1394/02/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravitreal Bevacizumab alone or in combination with 1 mg Triamcinolone in diabetic macular edema

Public title

effect of Bevacizumab alone or in combination with 1 mg Triamcinolone for treatment of diabetic retina swelling

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: bilateral macular edema with foveal

involvement; Visual acuity between 20/40-20/400; Age more than 20; HbA1c more less than 10; Blood pressure less than 160/100. Exclusion criteria: previous panretinal or focal laser photocoagulation; prior vitreoretinal surgery or injection; unilateral cataract surgery; history of glaucoma or ocular hypertension; VA worse than 20/400; proliferative diabetic retinopathy; significant media opacity; Monocularity; Central macular thickness>320; pregnancy; serum creatinine>3 mg/dl; other retinal diseases; unilateral cataract surgery; Cataract surgery during last 3 months; macular ischemia (Foveal avascular zone>100); uncontrolled blood pressure or diabetes with medication; previous corticosteroid consumption during last 3 months; HbA1c>10

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Farabi eye hospital ethic committee / Tehran
University Of Medical Science

Street address

Farabi eye hospital-Qazvin Sq.

City

Tehran

Postal code

Approval date

2013-05-30, 1392/03/09

Ethics committee reference number

ERC/R/332

Health conditions studied

1

Description of health condition studied

Diabetic Macular Edema

ICD-10 code

H36.0

ICD-10 code description

Diabetic retinopathy

Primary outcomes

1

Description

Visual acuity

Timepoint

At baseline before injection and then 2 weeks, 4 weeks, 6 weeks, 8 weeks, 12 weeks, 6 months, 12 months and 24 months after first injection

Method of measurement

Snellen chart

2

Description

Macular Thickness

Timepoint

At baseline before injection and then 2 weeks, 4 weeks, 6 weeks, 8 weeks, 12 weeks, 6 months, 12 months and 24 months after first injection

Method of measurement

Optical coherencetomography(Heidelberg spectralis
Sd)(roct/germany)OCT

Secondary outcomes

1

Description

Lens Cataract

Timepoint

Base line and each 2 months after injection

Method of measurement

Slit-lamp Examination

2

Description

Intraocular Pressure

Timepoint

At baseline before injection and then 2 weeks, 4 weeks, 6 weeks, 8 weeks, 12 weeks, 6 months, 12 months and 24 months after first injection

Method of measurement

Goldman tonometry

Intervention groups

1

Description

For the IVB group, 0.05 ml (1.25 mg) of bevacizumab

was injected intravitreally with a 27-gauge needle through the supratemporal quadrant.

Category

Treatment - Drugs

2

Description

For the IVB+IVT group, 0.05 ml (1.25 mg) of Bevacizumab was injected intravitreally with a 27-gauge needle through the infratemporal quadrant in combination with 0.025 ml of Triamcinolone(1mg).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Eye Hospital

Full name of responsible person

Hamid Riazi Esfahani

Street address

Farabi Eye hospital- Qazvin Sq

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vice-chancellor for research-Tehran University of Medical Science

Full name of responsible person

Dr.Mohammad Riazi Esfahani

Street address

Tehran University of Medical Science- Poorsina St.- 16th Azar Ave.

City

Tehran

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-Tehran University of Medical Science

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

Eye research center, Farabi Eye Hospital

Full name of responsible person

Hamid Riazi Esfahani

Position

Resident of ophthalmology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Eye research center, Farabi Eye Hospital

Full name of responsible person

Mohammad Riazi Esfahani

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Professor of ophthalmology/ director of eye research center

Other areas of specialty/work

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Position

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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