Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of the effect of intravitreal Bevacizumab (Avastin) injection alone or in combination with Diclofenac on the visual acuity of patients with diabetic macular edema

Protocol summary

Summary

This is a double blind randomized monocentric clinical trial. The aim of this study is the evaluation of the effect of intravitreal Bevacizumab alone or in combination with Diclofenac in improvement of macular edema in diabetic patients. 68 eyes of eligible patients according to inclusion criteria (such as diagnosed as center involving diabetic macular edema (DME) case, has no history of previous surgery or intraocular injection, visual acuity between 20/320 to 20/40) were enrolled randomly. After obtaining informed consent, complete ocular examination is done included of best corrected visual acuity (BCVA), refraction, slit lamp biomicroscopy, tonometry, fundoscopy, fundus photography, fluorescein angiography, optical coherence tomography. After that the eyes are randomly grouped for intravitreal injection of either Bevacizumab (1.25 milligrams in 0.1 milliliter) or Bevacizumab (1.25 milligrams in 0.1 milliliter) and Diclofenac (300 micrograms/0.1 milliliter). Visual acuity, central macular thickness, macular volume, intraocular pressure and refraction are evaluated both before and one month after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512144786N3**
Registration date: **2016-01-29, 1394/11/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-01-29, 1394/11/09

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-11-21, 1393/08/30

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of intravitreal Bevacizumab (Avastin) injection alone or in combination with Diclofenac on the visual acuity of patients with diabetic macular edema

Public title

Comparison of intravitreal Bevacizumab (Avastin) injection alone or in combination with Diclofenac in the treatment of diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria

Patients with these criteria were enrolled: diagnosed as center involving diabetic macular edema (DME), have no history of previous surgery, intraocular injection, diagnosis of glaucoma or ocular hypertension, visual acuity between 20/320 to 20/40, absence of iris neovascularization and significant opacities of ocular media, who are not monocular and are not pregnant. The exclusion criteria were: any previous hypersensitivity reaction to Bevacizumab or Diclofenac, complications such as endophthalmitis or intraocular pressure rise, refusal of patient or his/her non-cooperation in follow ups.

Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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
Hezar jerib St., Isfahan, Iran
City
Isfahan
Postal code
Approval date
2014-10-29, 1393/08/07
Ethics committee reference number
394740

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
Central macular thickness
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Optical coherence tomography

2

Description
Macular volume
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Optical coherence tomography

3

Description
Best corrected visual acuity
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Snellen chart

Secondary outcomes

1

Description
Refractive error
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Auto refractometer

2

Description
Intraocular pressure
Timepoint
Before intervention and 4 weeks after intervention
Method of measurement
Goldmann tonometer

Intervention groups

1

Description
The first group is treated by 1.25 milligrams in 0.1 milliliter Bevacizumab (Avastin) intravitreally.
Category

Treatment - Drugs

2

Description
The second group is treated by 1.25 milligrams in 0.1 milliliter Bevacizumab (Avastin) and 300 micrograms in 0.1 milliliter Diclofenac intravitreally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Feiz Hospital
Full name of responsible person
Dr. Heshmatollah Ghanbari
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Qods Sq., Isfahan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Mehdi Nematbakhsh
Street address
Hezar jerib St., Isfahan, Iran
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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
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

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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