

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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, funduscopy, 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

Name

Seyed Ali Sonbolestan

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1233 1401

Email address

sonbolestan@edc.mui.ac.ir

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

Street address

Qods Sq., Isfahan, Iran

City

Isfahan

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

City

Isfahan

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

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Sonbolestan

Position

Resident of Ophthalmology

Other areas of specialty/work

Street address

Feiz Hospital, Qods Sq., Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3445 2031

Fax

Email

sonbolestan@edc.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Sonbolestan

Position

Resident of Ophthalmology

Other areas of specialty/work

Street address

Feiz Hospital, Qods Sq., Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3445 2031

Fax

Email

sonbolestan@edc.mui.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Sonbolestan

Position

Resident of Ophthalmology

Other areas of specialty/work

Street address

Feiz Hospital, Qods Sq., Isfahan, Iran

City

Isfahan

Postal code

Phone

+98 31 3445 2031

Fax

Email

sonbolestan@edc.mui.ac.ir

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