

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of combination injection of intravitreal methotrexate and avastin with avastin in diffused diabetic macular edema in diabetic patient in isfahan faiz hospital 2017-2018

Protocol summary

Summary

Study purpose: comparison of combination injection of intravitreal methotrexate and avastin with avastin in diffused diabetic macular edema in diabetic patient, we can use this treatment if it was effective for prevention of disease and improved patient visual acuity in combination with other treatments. Study Design: clinical trial, single blind and randomized, single center. Time of study: 2017-2018 Location of study: Iran, Isfahan Faiz hospital Methods: the 22 patients were selected from the non-treat NPDR patients that come to Isfahan eye clinic Faiz hospital. After selection of patients with inclusion criteria and get informed letter of satisfaction they come to study. the treatment protocol is monthly injection of 1.25 microgram avastin in 0.05 millilitre in one eye and injection of every 15 days, 1.25 microgram avastin in 0.05 millilitre and methotrexate 400 microgram periodical in other eye.in the end of every month, before next injection we get OCT imaging of every eye that exist in Faiz hospital. The visual acuity is taken with snellen chart and in the last comparison with each other. Injections are every month since 3 times. Visual acuity, CMT and CMV is gotten one month after the last injection of avastin. Inclusion Criteria: 1- Adult patients (18 years and older) with clinically significant macular edema (CSME) with visual acuity less than 20/50 to Hand motion in the study eye. 2- Optical coherence tomography (OCT) scan demonstrating more than 300 microns central macular edema. 3- Ability to understand study instructions, interventions and potential complications. 4- History of reasonably controlled Diabetes mellitus (DM), \leq 8.5HbA1c that has been evaluated in the last 3 months. 5-Ability to undergo contraceptive protection during and 3 months after intraocular injections of methotrexate. 6- Clear understanding of teratogenic potential of MTX. Exclusion Criteria: 1- History of allergy to MTX. 2- An ocular condition is present such that, in the opinion of

the investigator, visual acuity loss would not improve from resolution of macular edema (e.g., foveal atrophy, pigment abnormalities, dense subfoveal hard exudates, nonretinal condition. 3- An ocular condition is present (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, epiretinal membrane, etc.). 4- An eye treated for Glaucoma 5- Eyes that underwent vitrectomy 6- History of intraocular malignancies. 7- Intraocular surgery with the prior 3 months. 8-Insulin usage less than a year. 9- Life threatening co morbidities such as cancer under therapy. 10- Use of oral, intravenous, periocular or intraocular corticosteroids (steroids) in prior 3 months. 11-Pregnant females. 12- Vitreous hemorrhage (active) in study eye 13-Media opacities 14-Herpetic disease of cornea 15-Corneal dystrophy with significant corneal edema Target sample size: 22 patients (44 eyes).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017090736088N1**
Registration date: **2017-09-26, 1396/07/04**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-26, 1396/07/04

Registrant information

Name

Behrooz Oliya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combination injection of intravitreal methotrexate and avastin with avastin in diffused diabetic macular edema in diabetic patient in isfahan faiz hospital 2017-2018

Public title

comparison of methotrexate vs avastin effect in patient with diabetic macular edema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Adult patients (18 years and older) with clinically significant macular edema (CSME) with visual acuity less than 20/50 to Hand motion in the study eye. 2- Optical coherence tomography (OCT) scan demonstrating more than 300 microns central macular edema. 3- Ability to understand study instructions, interventions and potential complications. 4- History of reasonably controlled Diabetes mellitus (DM), \leq 8.5HbA1c that has been evaluated in the last 3 months. 5-Ability to undergo contraceptive protection during and 3 months after intraocular injections of methotrexate. 6- Clear understanding of teratogenic potential of MTX. Exclusion Criteria: 1- History of allergy to MTX. 2- An ocular condition is present such that, in the opinion of the investigator, visual acuity loss would not improve from resolution of macular edema (e.g., foveal atrophy, pigment abnormalities, dense subfoveal hard exudates, nonretinal condition. 3- An ocular condition is present (other than diabetes) that, in the opinion of the investigator, might affect macular edema or alter visual acuity during the course of the study (e.g., vein occlusion, uveitis or other ocular inflammatory disease, neovascular glaucoma, epiretinal membrane, etc.). 4- An eye treated for Glaucoma 5- Eyes that underwent vitrectomy 6- History of intraocular malignancies. 7- Intraocular surgery with the prior 3 months. 8-Insulin usage less than a year. 9- Life threatening co morbidities such as cancer under therapy. 10- Use of oral,

intravenous, periocular or intraocular corticosteroids (steroids) in prior 3 months. 11-Pregnant females. 12- Vitreous hemorrhage (active) in study eye 13-Media opacities 14-Herpetic disease of cornea 15-Corneal dystrophy with significant corneal edema

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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**

eye research center of isfahan university of medical sciences

Street address

eye research center of isfahan university of medical sciences, Faiz hospital, Ghods square, Isfahan

City

Isfahan

Postal code

81469

Approval date

2016-12-07, 1395/09/17

Ethics committee reference number

IR.MUI.REC.1396.3.085

Health conditions studied**1****Description of health condition studied**

diabetic macular edema

ICD-10 code

E-10-E-14

ICD-10 code description

h-36

Primary outcomes

1

Description

visual acuity

Timepoint

at the beginning and before each intervention and one month after the last intervention

Method of measurement

snellen chart in fraction of 10

2

Description

central macular thickness

Timepoint

at the beginning and before each intervention and one month after the last intervention

Method of measurement

in micrometer with OCT imaging

3

Description

central macular volume

Timepoint

at the beginning and before each intervention and one month after the last intervention

Method of measurement

in microlitre with OCT imaging

4

Description

intra ocular pressure

Timepoint

at the beginning and before each intervention and one month after the last intervention

Method of measurement

with goldman tonometer in mmHg

5

Description

foveal avascular zone

Timepoint

at beginning and one month after the last intervention

Method of measurement

in square millimeter with OCT imaging

6

Description

endothelial cell count

Timepoint

at beginning and one month after the last intervention

Method of measurement

cells per square millimeter with specular microscopy

Secondary outcomes

1

Description

visual acuity

Timepoint

at the beginning of study and after each intervention and one month after last intervention

Method of measurement

with snellen chart in fraction of 10

2

Description

central macular thickness

Timepoint

at the beginning of study and after each intervention and one month after last intervention

Method of measurement

in millimeter in OCT imaging

3

Description

central macular volume

Timepoint

at the beginning of study and after each intervention and one month after last intervention

Method of measurement

in millilitre in OCT imaging

4

Description

foveal avascular zone

Timepoint

at the beginning and after last intervention

Method of measurement

in millimeter in fluorescein Angiography

5

Description

corneal endothelial cell count

Timepoint

at the beginning and after last intervention

Method of measurement

in cells per square millimeter with specular microscopy

6

Description

intraocular pressure

Timepoint

at the beginning of study and after each intervention and one month after last intervention

Method of measurement

millimeter Hg with goldman tonometer

Intervention groups

1

Description

in the patients eye that randomized is selected, we injected methotrexate and avastin periodically and every 15 days.methotrexate is injected 400 microgram and 0.16ml and after that 0.10cc AC tap.at once the other eye washing and put the measure on conjunctiva. avastin injection is performed on both eyes,1.25mlg in 0.05 in 4mm of limbus.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

eye clinic of isfahan faiz hospital

Full name of responsible person

behrooz oliya

Street address

blind alley22-chaharbaghpaeen-isfahan

City

isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

eye research center of isfahan university of medicine

Full name of responsible person

farhad fazel

Street address

faiz hospita -ghods squer-lisfahan

City

isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

eye research center of isfahan university of medicine

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 of isfahan university of medicine

Full name of responsible person

behrooz oliya

Position

resident of ophthalmology

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

eye reseach center of isfahan university of medicine

Full name of responsible person

farhad fazel

Position

ophthalmologist-vitreoretinal surgen-associated professor of isfshsn university of medicine

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

eye research center of isfahan university of medicine

Full name of responsible person

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Other areas of specialty/work**Street address**

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Fax
Email
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