Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 mililitre in one eye and injection of every 15 days, 1.25 microgram avastin in 0.05 mililitre 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), ≤ 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 methtrexate. 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

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Iran (Islamic Republic of)
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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), ≤ 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 methtrexate. 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 begining and befor each intervention and one month after the last intervention
Method of measurement
snellen chart in fraction of 10

2

Description
central macular thichness
Timepoint
at the begining and befor 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 begining and befor 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 begining and befor each intervention and one month after the last intervention
Method of measurement
with goldman tonometer in mmHg

5

Description
foveal avascular zone
Timepoint
at begining and one month after the last intervention
Method of measurement
in square millimeter with OCT imaging

6

Description
endothelial cell count
Timepoint
at begining and one month after the last intervention
Method of measurement
cells per squre millimeter with specular microscopy

Secondary outcomes

1

Description
visual acuity
Timepoint
at the begining of study and after each intervention and one month after last irtervention
Method of measurement
with snellen chart in fraction of 10

2

Description
central macular thickness
Timepoint
at the begining of study and after each intervention and one month after last irtervention
Method of measurement
in millimeter in OCT imaging

3

Description
central macular volume
Timepoint
at the begining of study and after each intervention and one month after last irtervention
Method of measurement
in millilitre in OCT imaging

4

Description
foveal avascular zone
Timepoint
at the begining and after last intervention
Method of measurement
in millimeter in floursein Angiography

5

Description
corneal endothelail cell count
Timepoint
at the begining and after last intervention
Method of measurement
in cells per squre millimeter with specular microscopy

6

Description
inrtaocular pressure
Timepoint
at the begining of study and after each intervention and one month after last irtervention
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 periodicaly 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

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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-associeted professor of isfshsn university of medicine

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eye research center of isfahan university of medicine

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Other areas of specialty/work

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City

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Postal code

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Phone

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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