

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

To evaluate the effect of single dose suprachoroidal triamcinolone acetonide injection combined with three monthly intravitreal injection of bevacizumab on center-involving diabetic macular edema in patients with non-proliferative diabetic retinopathy compared to the control group.

Protocol summary

Study aim

To compare the effects of single dose suprachoroidal triamcinolone acetonide injection combined with three monthly intravitreal injections of bevacizumab with only 3 monthly intravitreal bevacizumab injections on center involving diabetic macular edema in patients with non-proliferative diabetic retinopathy.

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

In this randomized, double-blind, two-arm, parallel-group controlled trial which will be held in Feiz eye hospital, we want to evaluate the effects of injecting a single dose triamcinolone acetonide in suprachoroidal space combined with 3 monthly intravitreal bevacizumab injections in patients with non-proliferative diabetic retinopathy with center involving diabetic macular edema.

Participants/Inclusion and exclusion criteria

Patients with non-proliferative diabetic retinopathy with center involving diabetic macular edema with best corrected visual acuity $\leq 20/40$.

Intervention groups

1- In the intervention group, 0.1 cc triamcinolone acetonide will be injected in suprachoroidal space combined with intravitreal bevacizumab in the first injection. Intravitreal bevacizumab alone will be injected in the second and third injections. 2- In the control group, combined with injecting intravitreal bevacizumab, a sham injection (pressing the sclera with the same needle) will be performed to simulate the suprachoroidal injection in the first session. Intravitreal bevacizumab alone will be injected in the second and third injections exactly the same as the intervention group.

Main outcome variables

1- Mean changes in best corrected visual acuity 2- Mean changes in central macular thickness 3- Mean changes in central macular volume 4- Mean changes in intraocular pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200314046761N1**

Registration date: **2020-03-21, 1399/01/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-21, 1399/09/01**

Update count: **1**

Registration date

2020-03-21, 1399/01/02

Registrant information

Name

Mohammadreza Fazel

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3629 2656

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To evaluate the effect of single dose suprachoroidal triamcinolone acetonide injection combined with three monthly intravitreal injection of bevacizumab on center-involving diabetic macular edema in patients with non-proliferative diabetic retinopathy compared to the control group.

Public title

Effect of single dose suprachoroidal triamcinolone acetonide injection on diabetic macular edema.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with non-proliferative diabetic retinopathy with center-involving diabetic macular edema with best corrected visual acuity $\leq 20/40$. Patients have not received any interventions (Intravitreal injection, laser, intraocular surgery) 3 months prior to the recruitment. No history of deep vitrectomy.

Exclusion criteria:

Other comorbid conditions such as CNV, RVO, Glaucoma etc. Pregnancy Significant cataract

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **59**

More than 1 sample in each individual

Number of samples in each individual: **2**

If eligible, each of the eyes of a single patient is included in the trial as one case.

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible eyes were randomly assigned into 2 group (intervention, control) using random block permutation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

1- At the onset, patients are completely informed about the trial and randomization process and they are blinded to the grouping. 2- The researcher cannot be blinded

because he performs all the interventions himself. However, mean best corrected visual acuity changes as the primary outcome are measured by a blinded resident. Central macular thickness (CMT), central macular volume (CMV) etc. as the secondary outcomes are measured by automatic spectral domain optical coherence tomography (SD-OCT) by a trained blinded technician. 3- The statistical analyst is blinded to the grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences (IR.MUI.REC).

Street address

No 84, Asiab Alley, Esta Nazar Street.

City

Isfahan

Province

Isfahan

Postal code

8173655734

Approval date

2019-11-02, 1398/08/11

Ethics committee reference number

IR.MUI.MED.REC.1398.410

Health conditions studied

1

Description of health condition studied

Center-involving diabetic macular edema

ICD-10 code

E08.311

ICD-10 code description

Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema.

Primary outcomes

1

Description

Mean change in best corrected visual acuity (BCVA)

Timepoint

Baseline (Day 0), a month after third intravitreal injection (Day 90-95)

Method of measurement

1- Snellen chart 2- Early Treatment Diabetic Retinopathy Study (ETDRS) letters

Secondary outcomes

1

Description

Mean changes in central macular thickness

Timepoint

Baseline (Day 0), a month after third intravitreal injection (Day 90-95)

Method of measurement

Spectral domain optical coherence tomography

2

Description

Mean changes in central macular volume

Timepoint

Baseline (Day 0), a month after third intravitreal injection (Day 90-95)

Method of measurement

Spectral domain optical coherence tomography

3

Description

Mean changes in intraocular pressure

Timepoint

Baseline (Day 0), day 30, a month after third intravitreal injection (Day 90-95)

Method of measurement

Applanation tonometry

Intervention groups

1

Description

Intervention group: Single dose suprachoroidal triamcinolone acetonide (4 mg / 0.1 cc) injection using custom made needle + intravitreal bevacizumab (1.25 mg / 0.05 cc) injections for 3 consecutive months

Category

Treatment - Drugs

2

Description

Control group: simulating suprachoroidal injection (sham injection: pressing the sclera with the same gauge needle without entering the sclera) in the first injection + intravitreal bevacizumab (1.25 mg / 0.05 cc) injections for 3 consecutive months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feiz eye hospital

Full name of responsible person

Dr.Farhad Fazel, Dr.Mohammadreza Fazel

Street address

Feiz eye hospital, Modarres Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Shaghaygh Haghjoo Javanmard

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr.Farhad Fazel, Dr.Mohammadreza Fazel

Position

Associate professor of Ophthalmolgy, Resident of ophthalmolgy

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Position

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

After the patients have been unrecognized, full data can be shared.

When the data will become available and for how long

The requests will be accepted at least 6 months after publishing the last results.

To whom data/document is available

Researchers in the field of ophthalmology

Under which criteria data/document could be used

-

From where data/document is obtainable

Mohammadeza Fazel

What processes are involved for a request to access data/document

Sending an email including the reason of request and personal curriculum vitae.

Comments