Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ≤ 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 sesson. 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

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Iran (Islamic Republic of)

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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 ≤ 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 committe of Isfahan University of Medical Sciences (IR.MUI.REC).

Street address

No 84, Asiab Alley, Esta Nazar Street.

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Isfehan

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
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Sponsors / Funding sources

1

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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
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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