

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of effect of Conventional and Optical coherence tomography Angiography-guided laser Photocoagulation to treatment of focal diabetic macular edema

Protocol summary

Study aim

Comparison of effect of Conventional and Optical coherence tomography Angiography-guided laser Photocoagulation to treatment of focal diabetic macular edema

Design

Patients referred to the clinic during one year who have focal macular edema due to diabetes and are indicated for treatment, are easily divided into two groups by simple sampling method without blindness and one in between. The number of samples is 40 people who are in two groups of 20. Randomizer software was used for randomization.

Settings and conduct

Tabriz Nikoukari Eye Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic patients referred to charity hospital with focal macular edema who are treated according to clinically significant macular edema criteria. Exclusion criteria: History of any retinal laser therapy; history of intraocular injection of anti-VEGF in the previous three months; evidence of severe macular ischemia on angiography ...etl

Intervention groups

After the initial examination and initial BCVA recording and initial OCT, patients are randomly divided into two groups. In the first group, without OCT-A, patients are treated with macular laser. Laser specifications include yellow wavelength duration: 0.1 and power between 80 to 150 and spot size is 50 micrometers, which is done at intervals of one spot in edematous areas. The goal is to change the light color to light gray in the laser-treated areas. In this group, we use the yellow wavelength with a duration: 0.1 and spot size: 50 micrometers with an intensity between 80 to 150 in the areas of microaneurysms. The goal is to change the light gray color in the place of microaneurysms.

Main outcome variables

Visual acuity; Macular thickness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210529051430N1**

Registration date: **2021-06-09, 1400/03/19**

Registration timing: **prospective**

Last update: **2021-06-09, 1400/03/19**

Update count: **0**

Registration date

2021-06-09, 1400/03/19

Registrant information

Name

farideh mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3657 7330

Email address

mousavif@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-20, 1400/03/30

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of effect of Conventional and Optical coherence tomography Angiography-guided laser Photocoagulation to treatment of focal diabetic macular edema

Public title
Laser treatment of macular edema with the help of angiography

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diabetic patients Focal macular edema Indication of treatment according to clinically significant macular edema criteria
Exclusion criteria:
 History of any retinal laser History of intraocular injection of anti-VEGF in the last three months Evidence of severe macular ischemia on angiography History of regional steroid injection in the last 4 months The presence of subfoveal edema Impossibility of laser due to insufficient vision History of any eye disease other than retinopathy, including uveitis glaucoma, degenerative diseases, and dystrophies Pregnant and lactating women Existence of diabetic nephropathy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Translation results University Committee of Ethics in Research, Tabriz University of Medic

Street address
Abbasi

City
Tabriz

Province
East Azarbaijan

Postal code
5154645395

Approval date
2021-04-12, 1400/01/23

Ethics committee reference number
IR.TBZMED.REC.1400.048

Health conditions studied

1

Description of health condition studied

Macular edema caused by diabetes

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

Patient vision

Timepoint

two months

Method of measurement

For this purpose, we analyze the data obtained from visual acuity based on LOGMAR between the two groups.

Secondary outcomes

1

Description

macular thickness

Timepoint

two months

Method of measurement

data collected from macular thickness based on microns using INDEPENDENT SAMPLE T TEST method between the two groups.

Intervention groups

1

Description

First group: patients undergo macular laser treatment without OCT-A. Laser specifications include yellow wavelength duration: 0.1 and power between 80 to 150 and spot size 50 micrometers, which is done at intervals

of one spot in edematous areas. The goal is to change the color light to light gray in the laser areas

Category

Treatment - Surgery

2

Description

Second group: After performing the OCT-A and locating the microaneurysms, laser therapy is performed. In this group, we use the yellow wavelength with duration: 0.1 and spot size: 50 micrometers with an intensity between 80 and 150 in the areas of microaneurysms. Light gray is present at the site of microaneurysms. Patients are followed up three times after the laser, at two-month intervals, including BCVA measurements and OCT. After collecting the data, they are analyzed and statistically analyzed

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Nikoukari Eye Hospital

Full name of responsible person

dr.Farideh Mousavi

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Abbasi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Farideh Mousavi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available