

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of optic nerve head perfusion in diabetic patients undergo conventional and micropulse macular photocoagulation

Protocol summary

Study aim

Comparison amount of optic head vesel density in micropulse and conventional befor and after photocoagulation

Design

One arm parallel group randomised in 50 eye, each group divide 25 eye, randomized trial with single randomization, odd numbers and even numbers

Settings and conduct

Alzahra eye hospital in Zahedan, after visits all pation ,diveide 2 group patients and under photocoagulation, pation do not know wich photocoagulation done.

Participants/Inclusion and exclusion criteria

Inter- non proliferation diabetes patients with macula edema No inter- patient with intra vitre injections

Intervention groups

First Intervention group for conventional photocoagulation and second Intervention group for micropulse photocoagulation these photocoagulation for improve macula edema, this study for effect of photocoagulations in optic head perfusion.

Main outcome variables

Vessel density and perfusion optic head

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221026056315N1**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **prospective**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

Maryam Zeighami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 8337

Email address

maryamzeighami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of optic nerve head perfusion in diabetic patients undergo conventional and micropulse macular photocoagulation

Public title

Comparison of optic nerve head perfusion in diabetic patients undergo conventional and micropulse macular photocoagulation in patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

non proliferative diabetic retinopathy patients with macula edema

Exclusion criteria:

Intravitrea drug injection

Age

From 30 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Use simple randomization, use the table of random number, even number will be assigned to micropulse intervention and odd number to conventional.

Randomization unit individual

Blinding (investigator's opinion)

Double blinded

Blinding description

People from the research team who are responsible for the selection and randomization of patients will not be included in the other stages of the research, especially the examination of people in terms of the dependent variable. Also, the consent form was filled and the procedure was explained, the patients and their companions will be divided without knowing that they were in the intervention or control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of zahedan university of medical sciences

Street address

Alzahra eye hospital, Motaheri street

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816737789

Approval date

2022-09-18, 1401/06/27

Ethics committee reference number

س-پ-۲-۸-۱۰۱-۱۴۰۲-۳۲۱۲

Health conditions studied

1

Description of health condition studied

Non proliferation diabetic patients with macula edema

ICD-10 code

E08.341

ICD-10 code description

Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema

Primary outcomes

1

Description

Optic head perfusion

Timepoint

Before conventional and micropulse photocoagulation - one month, 3 month and 6 month after conventional and micropulse photocoagulated

Method of measurement

Optical coherence tomography angiography(OCTA)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1 : Diabetic patients with macula edema one time under micropulse photocoagulation. This device (manufactured by Quantel Medical, USA) will be used with an adjustable power starting at 1000 mV with a duration of 300 μ s and a duty cycle of 15% and a spot size of 500 μ m.

Category

Treatment - Other

2

Description

Intervention group2: Diabetic patients with macula edema one time under conventional photocoagulation. Conventional laser photocoagulation (Quantel-medical Co, USA) will be performed via dilated pupil in eyes of second group as described below: adjustable power with 50 to 100 microns spot size, 0.1 second duration time. Focal laser will be applied in distance of 500 to 3000 microns of the foveal avascular zone (FAZ) and also on microvascular lesions of the exudative ring, also grid laser will be applied on thickened retinal areas in 500 microns distance of the FAZ and 500 microns distance of temporal ridge of optic disc.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra eye hospital Zahedan

Full name of responsible person

Maryam Zeighami

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

University

Street address

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public@zaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Zeighami

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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)**

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

Not applicable

Data Dictionary

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