

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of topical interferon $\alpha 2b$ as a complementary treatment of macular edema of patients with diabetic retinopathy in comparison with placebo, double blind randomized placebo controlled clinical trial

Protocol summary

Summary

Objectives: to evaluate the effect of topical interferon $\alpha 2b$ as a complementary treatment of macular edema of patients with diabetic retinopathy. Design: randomized, double blind, control with placebo, monocenter, first phase of clinical trial. Setting and conduct: population study: Major Inclusion criteria: patient with diabetic macular edema. Major Exclusion criteria: patients with positive history of radiotherapy or treatment with immunosuppressive agents; patients with malignancy or who have undergone organ transplant; patients with previous ocular vascular accident; patients who have had cataract surgery in the past 3 months. Sample size: 50 patients. Intervention: All patients will be checked for Fasting blood sugar, HbA1C, 2 hour post prandial glucose level. ophthalmic examination will be done for them. They will have macular OCT, fundus photography and fluorescein angiography basically and visual acuity will be evaluated. Patients will be divided into 2 groups, they all receive standard treatment of DME (intravitreal bevacizumab or focal laser). One group of them will receive topical interferon 1 million unit per milliliter as an adjunctive treatment for every 6 hours during 4 weeks and the other will get artificial tear as placebo. Duration of intervention: 4 weeks. Main outcome measures: visual acuity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081529370N1**

Registration date: **2016-10-26, 1395/08/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-26, 1395/08/05

Registrant information

Name

Aidin Meshksar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 2168

Email address

meshksaray@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences.

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical interferon $\alpha 2b$ as a complementary treatment of macular edema of patients with diabetic retinopathy in comparison with placebo, double blind randomized placebo controlled clinical trial

Public title

Clinical trial for evaluation of the effect of topical interferon $\alpha 2b$ as a complementary treatment of macular edema of patients with diabetic retinopathy compared with placebo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient with diabetic macular edema.

Exclusion criteria: patients with positive history of radiotherapy or treatment with immunosuppressive agents; patients with malignancy or who have undergone organ transplant; patients with previous ocular vascular accident; patients who have had cataract surgery in the past 3 months.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

patients are divided into intervention and control group by blocked randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Central building of Shiraz University of Medical Sciences, Zand street, Shiraz.

City

Shiraz

Postal code

71348-14336

Approval date

2016-07-23, 1395/05/02

Ethics committee reference number

IR.SUMS.MED.REC.1395.31

Health conditions studied

1

Description of health condition studied

diabetic retinopathy

ICD-10 code

H36.0

ICD-10 code description

Diabetic retinopathy

Primary outcomes

1

Description

macular thickness

Timepoint

before intervention, 4 wks after start of intervention, 4 wks after the end of intervention

Method of measurement

hidelberg OCT

2

Description

visual acuity

Timepoint

before intervention, 4 wks after start of intervention

Method of measurement

snellen chart

Secondary outcomes

1

Description

leakage on fluorescein angiography

Timepoint

before intervention, 4 wks after start of intervention

Method of measurement

fluoresceine angiography

Intervention groups

1

Description

Intervention group: The patients in this group receive topical Interferon alpha 2 b with dosage of 1 million unit per milliliter in the same container of placebo, 4 times a day. one milliliter of Interferon alpha 2b, 3 million units per milliliter produced by Pooyesh Daru company is combined with 2 milliliters of NaCl 0.09 solution and is kept in refrigerator for 10 days. The patient are examined on the week 2, 4, 8 during study.

Category

Treatment - Drugs

2

Description

Control group: The patients in this group receive artificial tear as placebo four times a day for 4 weeks and are examined on week 2,4 and 8 during study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari polyclinic of Shiraz University of Medical Sciences

Full name of responsible person

Aidin Meshksar

Street address

otahari polyclinic of Shiraz University of Medical Sciences, Namazi square, Shiraz.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Dr Basir Hashemi

Street address

Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Aidin Meshksar

Position

Ophthalmology Resident

Other areas of specialty/work

Street address

Khalili Hospital, Khalili street, Shiraz

City

Shiraz

Postal code

Phone

+98 713671382

Fax

Email

meshksaray@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Afarid

Position

Vitreoretina Fellowship

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Postal code

Phone

+98 71 3627 1382

Fax

Email

afaridm@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Afarid

Position

Vitreoretinal Fellowship

Other areas of specialty/work

Street address

Shiraz University of Medical Sciences, Zand street, Shiraz

City

Shiraz

Postal code

71345-1978

Phone

00

Fax

Email

afaridm@sums.ac.ir

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