

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effect of Garlic tablet 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

Study aim

Determination the effect of Garlic tablet as a complementary treatment of macular edema in diabetic retinopathy patients compared with placebo.

Design

Clinical trial with control group, double-blind, randomized, on 96 patients Patients are divided into two groups by using a random numbers .

Settings and conduct

Patients are selected from Shiraz clinics and were randomly assigned to two groups: case and control. All patients receive standard treatment for macular diabetic edema (intravenous injection of Bevacizumab or retinal laser) under the supervision of a physician. The therapist has no information about the case and control individuals. patients on the case group are given garlic tablets at a dose of 1000 mg daily for 4 weeks (2or 3 months if possible for some patients). The other group is given a placebo in the form of a pill with the same packaging as the Garlic supplement.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic patients with macular edema
Exclusion criteria: 1) Oral or intravenous injection of corticosteroids and Immunomodulatory therapy 2) History of vitrectomy surgery 3) Warfarin and Plavix and Heparin 4) History of chemotherapy and active gastrointestinal ulcers

Intervention groups

Intervention group: Patients receive Garlic tablet with a dose of 1000 mg daily Control group: Patients in the control group receive placebo tablet daily. After 1 month, the best corrected visual acuity and optical coherence tomography is performed and macula thickness is measured in both groups. Treatment duration: 1 months (if possible for some patients 2 or 3 months).

Main outcome variables

Best corrected visual acuity Optical coherence

tomography

General information

Reason for update

If possible the period of intervention will be extended up to 1or 2 months for some of the volunteers.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200415047083N1**

Registration date: **2020-07-14, 1399/04/24**

Registration timing: **prospective**

Last update: **2020-10-10, 1399/07/19**

Update count: **1**

Registration date

2020-07-14, 1399/04/24

Registrant information

Name

Mehrdad Afarid

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3629 1779

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Garlic tablet 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

Evaluation of the effect of Garlic tablet as a treatment of macular edema of patients with diabetic retinopathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetic patients with macular edema

Exclusion criteria:

Oral or intravenous injection of corticosteroids and Immunomodulatory therapy History of vitrectomy surgery Warfarin and Plavix and Heparin History of chemotherapy and active gastrointestinal ulcers History of cerebral hemorrhage

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

In each clinic a random number (for example between 0-1) is produced by calculator or computer for each patient and if this number is lower than a limit number (for example 0.5) that patient is selected as a case and if upper as a control or viceversa. Or : A number is allocated to each patient .Random numbers(equal to number of case or control group) produced by using calculator or computer .Patients are divided into two groups by using random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients were randomly assigned to two groups: case and control. All patients receive standard treatment for macular diabetic edema (intravenous injection of Bevacizumab or retinal laser) under the supervision of a physician. The therapist has no information about the case and control individuals.patients on the case group are given garlic tablets at a dose of 1000 mg daily for 4 weeks (if possible 2or 3 months for some patients). The other group is given a placebo in the form of a pill with the

same packaging as the Garlic supplement.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

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Department of Ophthalmology, Poostchi Ophthalmology Research Center, Asadabadi Ave., Zand Blvd., Shiraz,

City

Shiraz

Province

Fars

Postal code

7134997446

Approval date

2020-04-26, 1399/02/07

Ethics committee reference number

IR.SUMS.MED.REC.1399.052

Health conditions studied**1****Description of health condition studied**

Macular edema in patients with diabetes

ICD-10 code

E11.311

ICD-10 code description

Diabetes mellitus with unspecified diabetic retinopathy with macular edema

Primary outcomes**1****Description**

Macula thickness

Timepoint

Before starting the intervention and 1 month later after taking garlic tablets and placebo

Method of measurement

Optical coherence tomography

Secondary outcomes

1

Description

Best Corrected Visual Acuity

Timepoint

Before starting the intervention and 1 month later after taking garlic tablets and placebo

Method of measurement

Snellen chart

Intervention groups

1

Description

Intervention group: A complete examination of the anterior and posterior segments is performed for patients in this group. and the best corrected visual acuity is measured based on the Snellen chart, and optical coherence tomography is done for all the patients. All patients receive standard treatment for macular diabetic edema (intravenous injection of Boasizumab or retinal laser). Patients in the intervention group receive Garlic tablet with a dose of 1000 mg daily with lunch for 1 month (if possible for some patients 2 or 3 months).After 1 month, the best corrected visual acuity and optical coherence tomography is performed and macula thickness is measured.

Category

Treatment - Drugs

2

Description

Control group: A complete examination of the anterior and posterior segments is performed for patients in this group. and the best corrected visual acuity is measured based on the Snellen chart, and optical coherence tomography is done for all the patients. All patients receive standard treatment for macular diabetic edema (intravenous injection of Boasizumab or retinal laser). Patients in the control group receive placebo tablet daily with lunch for 1 month (if possible for some patients 2 or 3 months).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

clinics of Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Afarid

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Elham sadegi

Position

ریالتسهیثدف خب خافاشمئمخلع

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehrdad Afarid

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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