

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of curcumin-piperine supplementation on cardiometabolic, inflammatory and oxidative stress factors and macular vascular density in optical coherence tomography angiography (OCTA) in patients with non-proliferative diabetic retinopathy.

Protocol summary

Study aim

Determination of the effect of curcumin-piperine supplementation on cardiometabolic, inflammatory and oxidative stress factors and macular vascular density in optical coherence tomography angiography (OCTA) in patients with non-proliferative diabetic retinopathy.

Design

Clinical trial, randomized, double-blind, randomized control group of 50 patients. Randomization is done using a valid website and 4-block method.

Settings and conduct

This clinical trial will be performed in the special clinic of Feyz Hospital. Curcumin piperine and placebo are given to the patient in exactly the same packages. Patients and researchers will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria • Age 30 to 65 years Diagnosis of diabetic retinopathy with the approval of an ophthalmologist, imaging, CT scan or PCR Definitive diagnosis of diabetes by a diabetic doctor (fasting blood sugar above 126 mg / dL measured twice or HbA1C greater than or equal to 6.5%)

Intervention groups

Intervention group: Capsules containing curcumin-piperine each containing 500 mg of curcumin and 5 mg of piperine twice a day. control group 2 capsules each containing 500 mg of maltodextrin

Main outcome variables

Before and after the intervention; fasting blood glucose , macular vascular density using optical coherence tomography angiography (OCTA), blood CRP, oxidative stress indices including total antioxidant capacity (TAC) and total oxidative capacity (TOS) and index Kidneys including creatinine, BUN, and blood triglycerides are evaluated.

General information

Reason for update

Due to the lack of access to the oxidative stress kit (TOS), there were minor changes in the outcomes.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201129049534N5**

Registration date: **2021-09-11, 1400/06/20**

Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**

Update count: **1**

Registration date

2021-09-11, 1400/06/20

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-06, 1400/07/14

Expected recruitment end date

2022-10-06, 1401/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title

The effect of curcumin-piperine supplementation on cardiometabolic, inflammatory and oxidative stress factors and macular vascular density in optical coherence tomography angiography (OCTA) in patients with non-proliferative diabetic retinopathy.

Public title

Effect of curcumin piperine in patients with non-proliferative diabetic retinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 30 to 65 years Diagnosis of diabetic retinopathy with the approval of an ophthalmologist, imaging, CT scan or PCR Definitive diagnosis of diabetes by a diabetic doctor (fasting blood sugar above 126 mg / dL measured twice or HbA1C greater than or equal to 6/5%)

Exclusion criteria:

Sensitivity to plant products such as turmeric and pepper Follow a special diet in the last 3 months Taking anticoagulants such as heparin, warfarin, aspirin, etc. Pregnancy and lactation Patient dissatisfaction Taking herbal medicines or supplements in the last 3 months Requires the use of anti-VEGF (Anti-vascular endothelial growth factor) Use of therapies including laser therapy, surgery and intraocular injections Having certain diseases such as congenital diseases, type 1 diabetes, immune deficiency, cancer Uncontrolled diabetes Consume less than 80% of the curcumin piperine supplement Report any adverse side effects after taking supplements If other treatments of the patient such as treatment of hypertension, hyperlipidemia, etc. are variable during the course of treatment.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done individually. Entry of each patient into the intervention or control group is done randomly with the help of 4 blocking. This is done using a reputable random number generation website. (Random

number generation website:
<https://www.sealedenvelope.com/simple-randomiser/v1/lits>)

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double blinded so that the researcher and the subjects will not know which group they belong to. For blinding, curcumin piperine and placebo capsules are prepared in the same shape, color and size. These capsules are coded by someone other than the researchers (A and B) and then the capsules are given to patients. Until the end of the study and after analyzing the data, researchers will not know about the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Vice-Chancellor in Research Affairs - Medical University of Isfahan

Street address

School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Hezar-jerib Avenue

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Approval date

2021-09-04, 1400/06/13

Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.253

Health conditions studied

1

Description of health condition studied

Diabetic retinopathy

ICD-10 code

E08.3

ICD-10 code description

Diabetes mellitus due to underlying condition with ophthalmic complications

Primary outcomes

1

Description

Macular artery density

Timepoint

At baseline and end of the study

Method of measurement

OCTA (Optical Coherence Tomography angiography) device

2

Description

C reactive Protein (CRP)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

3

Description

Superoxide dismutase

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

4

Description

Total antioxidant capacity

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

5

Description

Fasting blood sugar

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

6

Description

triglycerides

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

7

Description

Malondialdehyde

Timepoint

At baseline and end of the study

Method of measurement

Commercial diagnostic kit

Secondary outcomes

1

Description

Blood urea nitrogen (BUN)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

2

Description

Creatinine (Cr)

Timepoint

At baseline and end of the study

Method of measurement

ELISA test

3

Description

Sleep Quality

Timepoint

At baseline and end of the study

Method of measurement

Pittsburgh sleep quality index (PSQI) questionnaire

4

Description

Emotional status (stress, anxiety, and depression)

Timepoint

At baseline and end of the study

Method of measurement

DASS-21 questionnaire

5

Description

Weight

Timepoint

At baseline and end of the study

Method of measurement

Digital Scale

Intervention groups

1

Description

Intervention group: Intervention group will receive a capsule containing curcumin-piperine in the amount of 500 mg of curcumin and 5 mg of piperine twice a day after breakfast and in the evening (a total of 1000 mg of curcumin and 10 mg of piperine daily) for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: The control group will receive capsules (2 capsules) containing placebo. Each capsule contains 500 mg of maltodextrin (a total of 1000 mg of maltodextrin daily) for 12 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Feyz Hospital

Full name of responsible person

sepide amini semiromi

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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

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

Mohammad Bagherniya

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study information will be published after the individuals are unidentified and after the project is completed.

When the data will become available and for how long

Access period starts six months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

For further analysis

From where data/document is obtainable

Dr. Mohammad Baghernia bagherniya@nutr.mui.ac.ir

What processes are involved for a request to access data/document

After reviewing the request and making it fully clear about the purposes of using the data, the data will be provided.

Comments