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
Mohammad bagherniya

Name of organization / entity

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Iran (Islamic Republic of)

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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/lists)

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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Quds Square, at the beginning of Modares Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Behruz Ataei

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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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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