

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of curcumin-piperine dietary supplement on lipid profile, glycemic, inflammatory and blood pressure indicators in people with type 2 diabetes and hypertriglyceridemia: randomized double-blind clinical trial

Protocol summary

Study aim

the effect of curcumin-piperine dietary supplement on lipid profile, glycemic, inflammatory and blood pressure indicators in people with type 2 diabetes and hypertriglyceridemia: randomized double-blind clinical trial

Design

The double-blind, phase 3 and randomized trial will be divided into two groups of 40 people (intervention group and placebo) using a random number table.

Settings and conduct

We select 80 people with type 2 diabetes with hypertriglyceridemia who go to clinics affiliated to Isfahan University of Medical Sciences and randomly divide them into two groups: supplement and placebo. For the purpose of blindness, the drug and the placebo will be very similar and participants and researchers will not be aware of it until the end of the study. Biochemical evaluation, anthropometry and measurement of blood pressure and blood test are performed at the beginning of the study and 12 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: willingness to participate in the study; age 18-65 years old; diagnosed with type 2 diabetes (fasting blood sugar above 126 mg / dL); hypertriglyceridemia (triglyceride above 150 mg / dL). Exclusion criteria: pregnancy or lactation; people with type 1 diabetes and diabetes insipidus; insulin injection; smoking; heart disease, lung disease, kidney disease, malignant cancer, immune system disorders, addiction or severe disease; unwillingness to continue cooperation; observation of any side effects; creating any of the conditions of non-inclusion during the study and taking less than 90% of curcumin supplement.

Intervention groups

Take one 500 mg curcumin-piperine tablet daily for 12

weeks. Placebo group: Take one placebo tablet daily for 12 weeks

Main outcome variables

Lipid profile (HDL, LDL, TG, TCh); fasting blood sugar (FBS); weight, height, waist circumference, BMI; blood pressure; insulin level; CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N50**

Registration date: **2021-02-16, 1399/11/28**

Registration timing: **registered_while_recruiting**

Last update: **2021-02-16, 1399/11/28**

Update count: **0**

Registration date

2021-02-16, 1399/11/28

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 1792 2110

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-10, 1399/09/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of curcumin-piperine dietary supplement on lipid profile, glycemic, inflammatory and blood pressure indicators in people with type 2 diabetes and hypertriglyceridemia: randomized double-blind clinical trial

Public title

The effect of curcumin-piperine dietary supplement in people with type 2 diabetes and hypertriglyceridemia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participate in the study Age: 18-65 years old Type 2 diabetes (fasting blood sugar above 126 mg / dL) Hypertriglyceridemia (triglyceride above 150 mg / dL) has been diagnosed.

Exclusion criteria:

Pregnancy and lactation People with type 1 diabetes and tasteless diabetes Insulin injection Smoking Heart, lung, kidney, malignant cancer, immune system disorders, addiction or mental illness

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be divided into two groups of intervention and placebo by simple random sampling and will be studied for 12 weeks. First, the list of patients who are admitted according to the inclusion criteria is prepared with the cooperation of the design specialist. Then, a code is assigned to each person and patients are divided into two groups of intervention and control using a table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to conduct this research in a double-blind

manner, before starting the study, the relevant capsules are coded in A and B by a person other than the researcher, so that the researcher does not know the type of capsules received by both participants and researchers.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib St.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-11-22, 1399/09/02

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.578

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

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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

Serum lipids

Timepoint

Blood samples are taken at the beginning and end of the study

Method of measurement

Blood samples

2**Description**

Blood glucose
Timepoint
Blood samples are taken at the beginning and end of the study
Method of measurement
Blood samples

Secondary outcomes

1

Description
Cholesterol
Timepoint
Before and after the intervention
Method of measurement
Blood samples using enzymatic methods

2

Description
High-density lipoprotein (HDL)
Timepoint
Before and after the intervention
Method of measurement
Blood samples using enzymatic methods

3

Description
Low density lipoprotein (LDL)
Timepoint
Before and after the intervention
Method of measurement
Blood samples using enzymatic methods

4

Description
Inflammatory factor (hs-CRP)
Timepoint
Before and after the intervention
Method of measurement
Blood samples using enzymatic methods

Intervention groups

1

Description
Intervention group: will receive one capsule daily (containing 495 mg of curcumin extract + 5 mg of piperine) along with diet and exercise recommendations. The supplement is from Sami labs Ltd., India and is used for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: they will receive one placebo capsule

daily, along with diet and exercise recommendations. The placebo is purchased from Sami labs Ltd., India and consumed for 12 weeks. Capsules are exactly the same in type, color, shape and size (appearance).

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
The endocrine and metabolism research center, Isfahan University of Medical Sciences.
Full name of responsible person
Dr. Gholamreza Askari
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Department of Community Nutrition, School of Nutrition and Food sciences, Isfahan University of Medical Sciences
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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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http://nutr.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Dr Gholamreza Askari
Position
MD & PhD (Nutritionist)
Latest degree
Specialist
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)

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

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

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Data can be shared after making people inaccessible

When the data will become available and for how long

One year after the results are published

To whom data/document is available

Researchers and academic and research institutes

Under which criteria data/document could be used

The data will be made available for research purposes and care must be taken to preserve that information

From where data/document is obtainable

Hezar Jerib St. Isfahan University of Medical Sciences

Faculty of Nutrition and Food Sciences Dr. Gholamreza

Askari ASKARI@MUI.AC.IR

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

Submit your application via email to be sent if you agree

ASKARI@MUI.AC.IR

Comments