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 sever 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

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Iran (Islamic Republic of)

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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
Isfehan
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

Street address

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

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou

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Isfahan, Hezargarib street, Esfahan university of medical sciences

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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
Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Gholamreza Askari

Position
Ph.D of nutrition, Assistant Professor

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