

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of supplementation with curcumin on serum lipid level in patients with type 2 diabetes mellitus and co-existence dislipidemia: A randomized placebo-controlled trial

Protocol summary

Study aim

Determining the effects of supplementation with curcumin on serum lipid level in patients with type 2 diabetes mellitus and co-existent dislipidemia

Design

A concealed, randomized, triple blind, placebo-controlled clinical trial with a parallel group design of 80 patients. Website "www.randomizer.org" will be used for generating randomization list.

Settings and conduct

Patients with type 2 diabetes mellitus and co-existent dislipidemia admitted to endocrinology clinic in Imam Reza Hospital in Mashhad are study population. Patients will be allocated to two study groups as intervention and placebo. Patients, researcher and assessors will be kept blind in this study. Lipid and glucose profile (FBS, HbA1C, 2hpp, LDL, HDL, TG, Cholesterol) will be assessed before and after intervention (12 weeks later) in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetic mellitus; co-existence of dyslipidemia; Patient consent to participate in the study. Non inclusion criteria: Pregnancy and breast feeding; malignancy; chronic liver disease; renal failure; chronic inflammatory disease; acute infection; other endocrine diseases; liver and bladder obstructive diseases

Intervention groups

Intervention group: curcumin (500mg) and piperin (5mg) with standard treatment for 12 weeks. Placebo group : placebo with standard treatment for 12 weeks.

Main outcome variables

Fasting blood sugar (FBS); Hemoglobin A1C (HbA1C); Low-density lipoprotein (LDL); High-density lipoprotein (HDL); Triglyceride (TG); Total Cholesterol

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130408012941N2**

Registration date: **2022-02-08, 1400/11/19**

Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**

Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 18988

Email address

morovatdarn@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-20, 1400/12/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of supplementation with curcumin on serum lipid level in patients with type 2 diabetes mellitus and co-existence dislipidemia: A randomized placebo-controlled trial

Public title

Curcumin effect in patients with type 2 diabetes mellitus and co-existent dislipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with with type 2 diabetes mellitus based on FPG $\geq$ 126 mg/dL, glycated hemoglobin (HbA1C) $\geq$ 6.5% OR treatment with antidiabetic drugs. Co-existence of dislipidemia Patient consent to participate in the study

Exclusion criteria:

Pregnancy and breast feeding Malignancy Chronic liver dysfunction (alt,ast >3 fold more than normal) Kidny dysfunction (cr>2) Chronic inflammatory diseases Acute infection diseases Endocrine diseases Psychology diseases Secondary causes of hypoglycemia Drug use Change the antidiabetic drugs Obstructive billiary and liver diseases History of gallbladder stones

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method, the random number sequences will be generated through <https://www.Randomization.com>. The random number sequences are determined for the required sample size (n=40 in each group). Following, after patients enter the study based on the inclusion criteria, according to the list of the random number sequences generated, individuals are allocated to one of the intervention and placebo groups, and this continues until the number of patients in each group is completed.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Using drugs with similar shape, smelling and color.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committees of Mashhad University of Medical Sciences

Street address

Clinical Reasearch Unit, Imam Reza Hospital, Ebne Sina street.

City

Mashhad

Province

Razavi Khorasan

Postal code

911379113316

Approval date

2021-11-23, 1400/09/02

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.596

Health conditions studied

1

Description of health condition studied

patients with type 2 diabetes mellitus and co-existence dislipidemia

ICD-10 code

E11.69

ICD-10 code description

Type 2 diabetes mellitus with other specified complication

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

before intervention and 12 weeks after intervention

Method of measurement

Lab test on blood sample

2

Description

LDL (low-density lipoprotein)

Timepoint

before intervention and 12 weeks after

Method of measurement

Lab test on blood sample

3

Description

Hemoglobin A1C
Timepoint
before intervention and 12 weeks after
Method of measurement
Lab test on blood sample

4

Description
HDL (High-density lipoprotein)
Timepoint
before intervention and 12 weeks after
Method of measurement
Lab test on blood sample

5

Description
TG (Triglyceride)
Timepoint
before intervention and 12 weeks after
Method of measurement
Lab test on blood sample

6

Description
Total Cholesterol
Timepoint
before intervention and 12 weeks after
Method of measurement
Lab test on blood sample

Secondary outcomes

1

Description
Body mass index
Timepoint
before intervention and 12 weeks after
Method of measurement
weight and height measurement

Intervention groups

1

Description
Intervention group: Patients with type 2 diabetes mellitus and co-existence dyslipidemia will receive curcumin 500 mg and piperidin 5mg with standard care for 12 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients with type 2 diabetes mellitus and co-existence dyslipidemia will receive placebo with standard care for 12 weeks.
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Solmaz Hasani
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Imam Reza Hospital, Ebne Sina St, Mashhad
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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
Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Solmaz Hasani

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Negar Morovatdar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Principal investigators are committed to presenting all the achievements of the project based on the Mashhad University of Medical Sciences protocol.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available