Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 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. Patinets will be allocated to two study groups as intervention and palcebo. Patients, researcher and assessors will be kept blind in this study. Lipid and glocuos 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 melitusis; co-existance 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≥ 126 mg/dL, glycated hemoglobin (HbA1C) ≥ 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
۹۱۳۷۹۱۳۳۱۶

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 hight mesurment

Intervention groups

1

Description

Intervention group: Patients with type 2 diabetes mellitus and co-existence dislipidemia will recieve 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 dislipidemia will recieve 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

Street address

Imam Reza Hospital, Ebne Sina St, Mashhad

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Morovatdarn@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour Mobarhan

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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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Imam Reza Hospita; Ebne Sina street
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Person responsible for scientific inquiries

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Person responsible for updating data

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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 achivements 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