Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of curcumin-piperine supplementation on Oxidized LDL and oxidative stress index in patients with type 2 diabetic with high LDL

Protocol summary

Study aim
Investigating the effect of curcumin-piperine supplementation on oxidative stress index and oxidized LDL in type 2 diabetic patients with high LDL

Design
Placebo-controlled clinical trial double blind by accident Phase 3 on 60 patients Using Excel software

Settings and conduct
In this study, patients with high LDL referring to Valiasr Hospital, Zanjan if they wish to participate in the study informed consent of them will be taken. After 12 to 14 hours of fasting, 5 cc of blood is taken to measure their blood serum concentrations of lipids, LDL oxidative, stress oxidative parameters and other serum biochemical parameters and kept in the freezer. Participants randomly using the divided randomly classified into two groups: supplement and placebo group.

Participants/Inclusion and exclusion criteria
5 to 10 years have passed since the onset of diabetes, Taking atorvastatin Glycosylated hemoglobin A1c (HbA1c) between 7 and 9% ,Patients will be included in the study if their LDL blood level is more than 100 mg/dL

Intervention groups
Patients group supplement will be received daily curcumin-piperine for three months and Patients in the control group will be received placebo daily.

Main outcome variables
Low Density Lipoprotein Cholestrol (LDL-C), High Density Lipoprotein Cholestrol (HDL-C), Triglyceride(TG), Total Cholestrol, Fasting Blood Sugar(FBS), HBA1C, LDL oxidative, MDA,SOD

General information

Reason for update
Acronym

IRCT registration information
IRCT registration number: **IRCT20230823059232N1**
Registration date: **2023-12-07, 1402/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2023-12-07, 1402/09/16**
Update count: **0**

Registration date
2023-12-07, 1402/09/16

Registrant information
Name
Negin Parsamanesh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 912 441 8600
Email address
neginparsa.684@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-11-06, 1402/08/15
Expected recruitment end date
2024-03-15, 1402/12/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of curcumin-piperine supplementation on Oxidized LDL and oxidative stress

index in patients with type 2 diabetic with high LDL

Public title
Evaluation the effect of curcumin-piperine supplementation on Oxidized LDL and oxidative stress index in patients with type 2 diabetic with high LDL

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
5 to 10 years have passed since the onset of diabetes Taking atorvastatin Glycosylated hemoglobin A1c (HbA1c) between 7 and 9% blood LDL level is more than 200 mg/dL

Exclusion criteria:
Pregnancy or breastfeeding Participating in concurrent trials Presence of malignancies r disease (alanine aminotransferase level three times the upper limit of the normal range) chronic live, renal failure chronic inflammatory diseases such as rheumatoid arthritis and acute infections thyroid disorders (such as hypothyroidism or hyperthyroidism) obsessive-compulsive disorder other types of diabetes receiving hormone or other herbal treatments hypersensitivity to curcuminoids

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Allocation software was used to randomize the sample into two treatment and placebo groups. Output of mentioned software includes a table that shows the number of each patient is located in each group (intervention or placebo)

Blinding (investigator's opinion)
Double blinded

Blinding description
This study has been designed as double-blind and persons including participants, and investigators, were kept unaware of the treatment administered. Drug and placebo vials have similar packaging and labeling and all recorded data will be encoded in the questionnaires and software.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of medical sciences

Street address
Karmandan

City
Zanjan

Province
Zanjan

Postal code
4513956184

Approval date
2023-09-26, 1402/07/04

Ethics committee reference number
IR.ZUMS.REC.1402.155

Health conditions studied

1

Description of health condition studied
type 2 diabetic patients with high levels of low-density lipoprotein

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
LDL-C

Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement

Method of measurement
Enzymatic method using a kit

2

Description
HDL-C

Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement

Method of measurement
Enzymatic method using a kit

3

Description
TG
Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement
Method of measurement
Enzymatic method using a kit

4

Description
Total Cholestrol
Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement
Method of measurement
Enzymatic method using a kit

5

Description
FBS
Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement
Method of measurement
Enzymatic method using a kit

6

Description
Malondialdehyde
Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement
Method of measurement
Enzyme method using kit

7

Description
Superoxide dismutase
Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement
Method of measurement
Enzyme method using kit

8

Description
Oxidized Ldl
Timepoint
From the beginning of the study (before the start of the intervention) and 90 days after the start of the curcumin-piperine supplement
Method of measurement
Enzyme method using kit

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 500m/gram curcumin per day for 3 months
Category
Treatment - Other

2

Description
Control group: Take placebo (500 mg of lactose) daily for 3 months
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Negin Parsamanesh
Street address
Valiasr square
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Shahin Besharati
Position
Assistant professor
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Person responsible for scientific inquiries

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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
Because the participant’s informations should remain confidental.

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

Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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