

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 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 Cholesterol (LDL-C), High Density Lipoprotein Cholesterol (HDL-C), Triglyceride(TG), Total Cholesterol, 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 liver, 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 Cholesterol

**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

**City**

Zanjan

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**Phone**

+98 912 441 8600

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neginparsa.684@gmail.com

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### 2

**Recruitment center****Name of recruitment center**

Valiasr hospital

**Full name of responsible person**

Shahin Besharati

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Zanjan University of Medical Sciences  
**Full name of responsible person**  
Shahin Beshrati  
**Street address**  
Valiasr hospital  
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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  
**Latest degree**  
Subspecialist  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

#### Contact

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Kamyar Mansouri  
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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 confidential.

### **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