Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Investigating the effect of curcumin-piperine supplementation on interleukin 6 and oxidative stress index in diabetic nephropathy patients

Protocol summary

Study aim

Determining the effect of curcumin-piperine supplementation on malondialdehyde levels in diabetic nephropathy patients Determining the effect of curcumin-piperine supplementation on superoxide dismutase level in diabetic nephropathy patients Determining changes in serum concentration of interleukin 6 in diabetic nephropathy patients receiving curcumin-piperine supplement compared to placebo

Design

Randomized, double-blind, placebo-controlled

Settings and conduct

randomized controlled trial that will be conducted in the clinic of Valiasr Hospital in Zanjan.60 patients will be selected who have type 2 diabetes and use oral antidiabetic drugs or insulin.

Participants/Inclusion and exclusion criteria

This study will be a randomized controlled trial that will be conducted in the clinic of Hazrat Waliasr Hospital in Zanjan. According to the previous study in this field, 60 patients will be selected who have type 2 diabetes and use oral antidiabetic drugs or insulin. The criteria for entering the study will be as follows: • Age ≥18 years • Type 2 diabetes and nephropathy • Estimated glomerular filtration rate (eGFR) ≥60 ml/min per 1.73 square meters • Controlled HTN (systolic). blood pressure [BP] <140 and diastolic blood pressure <90). Exit criteria History of gallstones, biliary obstruction (due to the adverse effect of curcumin on these cases), drug intolerance, or the patient's lack of cooperation and the use of chemotherapy drugs (such as methotrexate, paclitaxel, etc.), NSAIDs, antibiotics (such as vancomycin) and herbal medicines that interfere with kidney function within two weeks before sampling.

Intervention groups

1- Patients receiving curcumin supplementation 2- Patients receiving placebo

Main outcome variables

Fasting Blood Sugar(FBS),HbA1C,Creatinine,Urine albumin, Malondialdehyde, Superoxide dismutase,Il-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230823059232N2**
Registration date: **2024-05-16, 1403/02/27**
Registration timing: **prospective**

Last update: **2024-05-16, 1403/02/27**
Update count: **0**

Registration date

2024-05-16, 1403/02/27

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

2024-05-21, 1403/03/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of curcumin-piperine supplementation on interleukin 6 and oxidative stress index in diabetic nephropathy patients

Public title
Investigating the effect of curcumin-piperine supplementation on interleukin 6 and oxidative stress index in diabetic nephropathy patients

Purpose
Other

Inclusion/Exclusion criteria

Inclusion criteria:
Age ≥18 years Type 2 diabetes and nephropathy Estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73 m2 Controlled HTN (systolic). blood pressure [BP] <140 and diastolic blood pressure <90)

Exclusion criteria:
History of gallstones and biliary obstruction Kidney transplant treatment Autoimmune disease or malignancy pregnancy liver damage History of organ transplantation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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
Valiasr hospital

City
zanjan

Province
Zanjan

Postal code
98

Approval date
2023-11-21, 1402/08/30

Ethics committee reference number
IR.ZUMS.REC.1402.162

Health conditions studied

1

Description of health condition studied
Type 2 diabetic patients with nephropathy

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
fasting blood suger

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
creatinine

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
urine albumine
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
Turbidometry

4

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
Eliza

5

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
eliza

6

Description
interleukin 6
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
eliza

7

Description
HbA1C
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

Secondary outcomes

empty

Intervention groups

1

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

2

Description
Control group: Placebo (500 mg of lactose) to be consumed 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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Zanjan
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Recruitment center
Name of 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
Private

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
Amirhossein Sahebkar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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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
ecause 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