

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 2026

The effects of Nano-curcumin on metabolic status in patients with diabetes on hemodialysis

Protocol summary

Study aim

The aim of this study is to determine the effects of Nano-curcumin supplementation on metabolic status in patients with diabetic hemodialysis.

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct

Akhavan Clinic, Kashan, Iran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diabetic hemodialysis patients; aged 18 to 80 Exclusion criteria: Patients suffering from infectious, inflammatory and malignant diseases. Patients taking curcumin supplements, antioxidant and/or anti-inflammatory supplements within 3 months before participation in the study. subjects receiving immunosuppressive and antibiotics medications.

Intervention groups

Patients will be assigned to receive Nano-curcumin supplements (n=30) and placebo (n=30).

Main outcome variables

Fasting blood samples will be taken at baseline and after 12-week intervention. Insulin and insulin resistance as primary outcomes and inflammatory factors, biomarkers of oxidative stress, and serum lipoproteins as secondary outcomes will be measured at baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150606022562N6**

Registration date: **2019-02-11, 1397/11/22**

Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**

Update count: **1**

Registration date

2019-02-11, 1397/11/22

Registrant information

Name

Fereshteh Bahmani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

fbahmani@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-06, 1397/08/15

Expected recruitment end date

2018-11-26, 1397/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Nano-curcumin on metabolic status in patients with diabetes on hemodialysis

Public title

The effect of Nano-curcumin in patients with diabetic hemodialysis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic hemodialysis patients Aged 18to 80 years

Exclusion criteria:

Patients suffering from infectious, inflammatory and malignant diseases. Patients taking curcumin supplements, antioxidant and/or anti-inflammatory supplements within 3 months before participation in the study. subjects receiving immunosuppressive and antibiotics medications.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline, after balanced blocked randomisation, participants will be allocated into two groups to take either Nano-curcumin supplements (n = 30) or placebos (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences and Health Services

Street address

Kashan University of Medical Sciences, Ravand road

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2018-11-05, 1397/08/14

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.065

Health conditions studied**1****Description of health condition studied**

Chronic kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes**1****Description**

Insulin

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

Elisa kit

2**Description**

Insulin resistance

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

Calculation using HOMA formula

Secondary outcomes**1****Description**

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2**Description**

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

High-density lipoprotein-cholesterol (HDL-Cholesterol)

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

High sensitive-C-reactive protein (hs-CRP)

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Elisa kit

5

Description

Total Nitric Oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

6

Description

Expression levels of PPAR- γ gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Real-Time PCR

7

Description

Expression levels of LDLR gene

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Real-Time PCR Method

8

Description

Gluthatione

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

Spectrophotometry

9

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

Spectrophotometry

10

Description

Malondialdehyde

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

Spectrophotometry

11

Description

Expression levels of TGF- β gene

Timepoint

At the beginning of the study and 12 weeks after intervention

Method of measurement

Real-Time PCR Method

12

Description

Fasting blood sugar

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

13

Description

VLDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

14

Description

LDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

15

Description

BUN

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

16

Description

Creatinine

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

17

Description

AGEs

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

18

Description

Systolic blood pressure (SBP)

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Sphygmomanometer

19

Description

Diastolic blood pressure (DBP)

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Intervention group: receiving one 80 mg Nano-curcumin capsule per day for 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo oral capsule, daily, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan clinin

Full name of responsible person

Fereshteh Bahmani

Street address

Ghotb-ravandi boulevard

City

Kashan

Province

Isfahan

Postal code

8719674591

Phone

+98 31 5534 2020

Fax

+98 31 5534 2025

Email

fbahmani@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Banafshe

Street address

Vice chancellor for research, Kashan University of Medical Sciences ,Ravand road

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 2999

Email

banafsheh_h@kaums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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**

Kashan University of Medical Sciences

Full name of responsible person

Fereshteh Bahmani

Position

Associate Professor/ Academic staff member of the
Department of Clinical Biochemistry

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Medical Faculty, Kashan University of Medical
Sciences, Ravand road

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Email

bahmani@kaums.ac.ir

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

Kashan University of Medical Sciences

Full name of responsible person

Fereshteh Bahmani

Position

Associate Professor/ Academic staff member of the
Department of Clinical Biochemistry

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Medical Faculty, Kashan University of Medical
Sciences, Ravand road

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Email

fbahmani@kaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Fereshteh Bahmani

Position

Associate Professor/ Academic staff member of the
Department of Clinical Biochemistry

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Medical Faculty, Kashan University of Medical
Sciences, Ravand road

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5554 0021

Email

fbahmani@kaums.ac.ir

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

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

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