Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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Iran (Islamic Republic of)

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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, particpants 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
Isfehan

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamid Reza Banafshe
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Vice chancellor for research, Kashan University of Medical Sciences ,Ravand road
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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
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
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Person responsible for updating data

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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