

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Effects of nano-curcumin supplementation on metabolic profiles in patients with diabetic foot ulcer

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of nano-curcumin supplementation on metabolic profiles in patients with diabetic foot ulcer (DFU).

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive supplements (n=30) or placebo (n=30)..

Settings and conduct

Among patients with DFU referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. Intervention period: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 45-85 years diagnosed with DFU. Exclusion Criteria: Patients with Severe renal insufficiency, unwillingness to cooperate.

Intervention groups

Intervention group: 80 mg nano-curcumin (Sina Pharmaceutical Company, Tehran, Iran), daily, for 12 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran) daily for 12 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles and inflammatory markers (secondary outcomes) will be quantified at study baseline and end-of-trial

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N51**

Registration date: **2019-03-22, 1398/01/02**

Registration timing: **retrospective**

Last update: **2019-03-22, 1398/01/02**

Update count: **0**

Registration date

2019-03-22, 1398/01/02

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-22, 1397/11/02

Expected recruitment end date

2019-02-21, 1397/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of nano-curcumin supplementation on metabolic profiles in patients with diabetic foot ulcer

Public title

Effect of nano-curcumin supplementation in treatment of diabetic foot ulcer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria: Patients with diabetic foot ulcer
Individuals aged 40 to 85 years..

Exclusion criteria:

Exclusion criteria: patients with Severe renal
insufficiency Unwillingness to cooperate.

Age

From **40 years** old to **85 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

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m²) and age (<65 and ≥65 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

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 at the Beheshti clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules. Supplements and placebo are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1397.105

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

Diabetic foot ulcer

ICD-10 code

E11.5

ICD-10 code description

Type 2 diabetes mellitus with circulatory complications

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

Insulin

Timepoint

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

Method of measurement

Elisa kit

2**Description**

Insulin resistance

Timepoint

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

Method of measurement

Calculation using HOMA formula

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

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

2

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

4

Description

Glutathione

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

7

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

8

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: 80 mg nano-curcumin (Sina Pharmaceutical Company, Tehran, Iran), daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran) daily for 12 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Clinic

Full name of responsible person

Dr. Mansooreh Heravi

Street address

Ghotbe Ravandi Boulevard, Kashan

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asemi_z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafsheh

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Kashan

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Isfahan

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1771844351

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banafsheh.hr@gmail.com

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
Zatollah Asemi

Position
PhD of Nutrition

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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