Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effects of nano curcumin supplementation in diabetic peripheral neuropathy

Protocol summary

Study aim
The effects of curcumin supplementation in diabetic peripheral neuropathy

Design
A total of 100 participants will be recruited and randomly assigned to 2 groups with a 1:1 allocation ratio. Random assignment will be done via block randomization.

Settings and conduct
Patients will be prescreened by telephone or face-to-face interview at 2 clinical of diabetes in Endocrinology and Metabolism Research Center (Tehran University of Medical Sciences, Tehran, Iran). Both active and placebo capsules (identical looking red coloured placebo capsules) will be manufactured by Sina Curcuminina (Exir Nano, Tehran, Iran). All of investigators and patients involve will be masked to the treatments assignments until the study will be completed.

Participants/Inclusion and exclusion criteria
To be eligible for the study, patients will be satisfy the following criteria: male or female patients between 30 and 70 years of age, a MNSI 2 or higher, abnormal NCS, normal folate levels and vitamin B12 levels. The main exclusion criteria from the study will be as follows: uncontrolled diabetes (HbA1c>8.5%), history of alcohol abuse, current smoker, current pregnancy or lactating women, diabetic foot , mental disease, heart failure, cancer, evidence of liver disease, impaired renal (GFR < 30), sensitivity to turmeric supplementation, current use of warfarin or other anticoagulant agents, and those with symptomatic peripheral vascular disease.

Intervention groups
The patients will be received 1 capsule of 40 mg of nano curcumin or 1 capsule of identical-looking placebo two times daily for 4 months.

Main outcome variables
The primary endpoint was patient-reported neuropathy screening instrument (MNSI), and Neuropathy disability score (NDS) changes at 4 months.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210925052566N2**
Registration date: **2022-03-29, 1401/01/09**
Registration timing: **prospective**

Last update: **2022-03-29, 1401/01/09**
Update count: **0**

Registration date
2022-03-29, 1401/01/09

Registrant information
Name
Sayed Mahmoud Sajjadi Jazi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 8822 0038
Email address
m_sajadi@tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-05-21, 1401/02/31
Expected recruitment end date
2023-02-19, 1401/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effects of nano curcumin supplementation in diabetic peripheral neuropathy

Public title
The effects of nano curcumin in diabetic peripheral neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients will eligible for recruitment with a MNSI of 2 or higher, abnormal NCS results and normal folate, vitamin B12 levels.
Exclusion criteria:
Exclusion criteria will be uncontrolled diabetes (HbA1c>8.5%), current pregnancy or lactating women, alcohol intake, current smoker, diabetic foot , mental disease, heart failure, cancer, evidence of liver disease (such as viral hepatitis, autoimmune hepatitis, etc.), impaired renal (GFR < 30), sensitivity to turmeric supplementation, current use of warfarin or other anticoagulant agents, and those with symptomatic peripheral vascular disease.
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
blocked randomization
Blinding (investigator's opinion)
Double blinded
Blinding description
Identical looking red coloured placebo capsules
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of National Institute for Medical Research Development
Street address
Shariati Hospital, Kargar Shomali Ave.
City
Tehran
Province
Tehran
Postal code
1411713135
Approval date
2021-11-30, 1400/09/09
Ethics committee reference number
IR.NIMAD.REC.1400.161

Health conditions studied

1

Description of health condition studied
Diabetes mellitus
ICD-10 code
E08.40
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description
1. Michigan neuropathy screening instrument (MNSI)
Timepoint
Baseline and 16 weeks
Method of measurement
Using standard scoring systems and questionnaires. Scoring is: Michigan neuropathy screening instrument , (0-10)

2

Description
Neuropathy disability score (NDS)
Timepoint
Baseline and 16 weeks
Method of measurement
Using standard scoring systems and questionnaires. Scoring is: Neuropathy disability score (0-10)

Secondary outcomes

1

Description
Pain score
Timepoint
Baseline and 16 weeks
Method of measurement
Patients will be asked to score pain on a visual analog scale 0-10 with 10 being the worst pain ever

2

Description

Fasting glucose, serum insulin, HOMA –IR, and HBA1c

Timepoint

Baseline and 16 weeks

Method of measurement

lab kit

3

Description

lipid profiles (HDL-c, LDL-c, TG, TC)

Timepoint

Baseline and 16 weeks

Method of measurement

lab kit

Intervention groups

1

Description

Intervention group: nanocurcumin

Category

Treatment - Drugs

2

Description

Control group: placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

2 clinical of diabetes in Endocrinology and Metabolism Research Center (Tehran University of Medical

Full name of responsible person

Sayed Mahmoud Sajjadi Jazi

Street address

Shariati Hospital, Kargar Shomali Ave.

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mahmood.sajadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development

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

National Institute for Medical Research Development

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

Tehran University of Medical Sciences

Full name of responsible person

Sayed Mahmoud Sajjadi Jazi

Position

Assistant professor of endocrinology

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

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Subspecialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is 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
Not applicable
Title and more details about the data/document
Data collected for the primary and secondary outcomes will be shared.
When the data will become available and for how long
Access starting 6 months after publication
To whom data/document is available
The data will only be available for people working in academic institutions.
Under which criteria data/document could be used
The data of the present study will only be accessible by for conducting Meta-analysis.
From where data/document is obtainable
To access the required data, the researchers can contact Dr. Sayed Mahmoud Sajjadi Jazi: email address: mahmood.sajadi@gmail.com
What processes are involved for a request to access data/document
The request will be assessed by the our group, and if all of us agree to the request, the requested data will be emailed.
Comments