

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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Shariati Hospital, Kargar Shomali Ave.

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Email

mahmood.sajjadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development

Full name of responsible person

Sayed Mahmoud Sajjadi Jazi

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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

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
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Asieh Mansour
Position
Assistant professor of Nutrition sciences
Latest degree
Ph.D.
Other areas of specialty/work
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asiehmansour@yahoo.com

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.sajjadi@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