

# 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

#### Street address

Shariati Hospital, Kargar Shomali Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

1411713135

#### Phone

+98 21 8822 0071

#### 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

### Street address

Shariati Hospital, Kargar Shomali Ave.,

### City

Tehran

### Province

Tehran

### Postal code

1411713135

### Phone

+98 21 84901

### Email

mahmood.sajjadi@gmail.com

### 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

#### Street address

Shariati Hospital, Kargar Shomali Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

1411713135

#### Phone

09802188220071

#### Email

mahmood.sajjadi@gmail.com

## 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**  
Internal Medicine  
**Street address**  
Shariati Hospital, Kargar Shomali Ave.  
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**Province**  
Tehran  
**Postal code**  
1411713135  
**Phone**  
09802188220071  
**Email**  
mahmood.sajjadi@gmail.com

## 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**  
Nutrition  
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**Province**  
Tehran  
**Postal code**  
1411713135  
**Phone**

09802188220071

**Email**  
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