

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Nano curcumin supplementation on the severity of diabetic sensorimotor polyneuropathy in type 2 diabetic patients : a double- blind randomized clinical trial

#### Protocol summary

##### Study aim

Determination of the Effect of Nanocurcumin Supplementation Compared to Placebo on the severity of diabetic sensorimotor polyneuropathy in type 2 diabetic patients.

##### Design

This study is conducted on 80 patients with diabetic polyneuropathy who have been admitted to the Diabetes Research Center. Patients are randomly divided into two groups: intervention and control groups and each participant is allocated a code.

##### Settings and conduct

This study is a double-blind, randomized, clinical trial on diabetic patients with neuropathy in Diabetic Research Center of Kermanshah University of Medical Sciences. Patients will be randomized into two groups of supplementation with curcumin and placebo for 8 weeks. Curcumin supplements are provided in the form of 80 mg capsules. A supplement will be consumed daily in the form of a capsules. Consuming supplement has been followed up in person every month. Meanwhile, once a week, the use of supplements is followed up by phone call. At the beginning and end of the study, from each person will taken two 24-hour meal reminders, and physical activity will be reviewed using the International Short Form Physical Activity Questionnaire (IPAQ). To determine the severity of neuropathy, the Toronto questionnaire will be used. Anthropometric evaluations are also performed. The study will be double blind, and the researcher and the patient will not get any supplementation information.

##### Participants/Inclusion and exclusion criteria

In this study, non-insulin type 2 diabetic patients with mild diabetic sensorimotor polyneuropathy will be included. People with other illnesses or those with neuropathies other than diabetic polyneuropathy will not be included in the study.

##### Intervention groups

Receiving nano-curcumin supplements formed of nanomixel curcumin particles, an effective ingredient in turmeric, by the intervention group and receiving placebo formed of all formulations of the drug except of curcumin, by the control group in the form of gel capsules of 80 milligrams from the Minoos Pharmaceutical Company Are being prepared. A 80 mg supplement will be consumed daily as a lunch capsule.

##### Main outcome variables

Severity of sensory-motor movement polyneuropathy; Blood pressure levels of fasting blood glucose, HbA1C and BS2hpg

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140413017254N5**

Registration date: **2017-12-28, 1396/10/07**

Registration timing: **prospective**

Last update: **2017-12-28, 1396/10/07**

Update count: **0**

##### Registration date

2017-12-28, 1396/10/07

##### Registrant information

##### Name

Gity Sotoude

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4293 3333

##### Email address

gsotodeh@tums.ac.ir

**Recruitment status****Recruitment complete****Funding source****Expected recruitment start date**

2018-01-21, 1396/11/01

**Expected recruitment end date**

2018-08-23, 1397/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of Nano curcumin supplementation on the severity of diabetic sensorimotor polyneuropathy in type 2 diabetic patients : a double- blind randomized clinical trial

**Public title**

Effect of Nano curcumin on the severity of diabetic sensorimotor polyneuropathy

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 30 to 60 years old desiration to participate in the study Body mass index between 25 - 39.9 Non-insulin diabetic patients type 2 Detection of mild sensorimotor polyneuropathy by using the Toronto questionnaire (score 6-8)

**Exclusion criteria:**

Follow a special diet during last month Sensitivity to curcumin Pregnancy and lactation Eat any nutritional supplement, vitamin and mineral supplement last month History of gastrointestinal ulcer and bile duct There are neuropathies other than the sensory-motor polyneuropathy diabetic diagnosed by a neurologist Take gabapentin and any medication Diseases diagnosed, such as cancer, liver, kidney, autoimmune diseases, inflammatory, thyroid and nervous and cardiovascular diseases, and drug use associated with these diseases

**Age**From **30 years** old to **60 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

**Randomization description**

For random allocation of individuals by statistic expert, permute-block randomization will be used for the two groups of study; thus, four blocks of AABB, ABAB, ABBA, BBAA, BABA, and BAAB are selected 20 times randomly and with placement, and The letters of the selected blocks will be written after each other. Stratified randomization will be used to control age and gender variables, based on the following categories: age (30-45, 46-60) and gender (male, female).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The researcher and the patient do not have any information on the type of supplement that they receive and they are prepared in the same way as in the form of tablets and supplements like nano-curcumin. A person who is not aware of the packet content will be asked to complete the naming of the supplement and the placebo in groups A and B. After collecting data at the end of the study, the codes of supplements will be specified for the researchers

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Central Building of Tehran University of Medical Sciences, Ghods st., Keshavarz Blv., Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2017-11-01, 1396/08/10

**Ethics committee reference number**

IR.TUMS.VCR.REC.1396.3838

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

Diabetic polyneuropathy

**ICD-10 code**

E11.43

**ICD-10 code description**

Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy

## Primary outcomes

### 1

#### Description

The severity of neuropathy in the Toronto questionnaire

#### Timepoint

Before the intervention, After intervention

#### Method of measurement

Toronto questionnaire

## Secondary outcomes

### 1

#### Description

Fasting Blood Sugar

#### Timepoint

Before the intervention, After the intervention

#### Method of measurement

KIT

### 2

#### Description

Blood sugar 2 hour after meal

#### Timepoint

Before the intervention, After the intervention

#### Method of measurement

KIT

### 3

#### Description

HBA1C

#### Timepoint

Before the intervention, After the intervention

#### Method of measurement

KIT

## Intervention groups

### 1

#### Description

Intervention group: Supplement that made of nano mucosal curcumin, an effective ingredient in turmeric, is prepared in the form of gelatin capsules of 80 milligrams from the Minoos Pharmaceutical Company. A 80 mg supplement will be consumed daily as a lunch capsule.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo, which consists of all drug formulation components except the effective curcumin agent, is prepared in the form of gel capsules of 80 mg

from Minoos Pharmaceutical Company. A 80 mg supplement will be consumed daily as a lunch capsule.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Therapeutic Center

##### Full name of responsible person

مهرعلی رحیمی

##### Street address

Taleghani Therapeutic Center, Shahid Beheshti Blvd., Kermanshah, Iran

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

3836798490

##### Phone

+98 38 3679 8490

##### Email

Taleghani\_Hospital@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Sahraeian

##### Street address

Ghods St., Keshavarz Blvd., Central Organization of Tehran university of Medical Sciences

##### City

Tehran

##### Province

Tehran

##### Postal code

2188955698

##### Phone

+98 21 8163 3698

##### Email

Info\_snsd@tums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Sara Asadi  
**Position**  
Master of nutrition  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
School of Nutrition, Tehran University Medical Sciences, Naderi St., Keshavar Blvd., Tehran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1439957181  
**Phone**  
+98 21 8895 5742  
**Email**  
sr.asadi11@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Gity Sotodeh  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
School of Nutrition, Tehran University of Medical Sciences, Naderi St., Keshavar Blvd., Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran

**Postal code**  
2188955698  
**Phone**  
+98 21 8895 5742  
**Email**  
gsotodeh@tums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Sara Asadi  
**Position**  
Master of Nutrition  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nutrition  
**Street address**  
School of Nutrition, Tehran University of Medical Sciences, Naderi St., Keshavar Blvd., Tehran, Iran  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
2188955698  
**Phone**  
+98 21 8895 5742  
**Email**  
sr.asadi11@yahoo.com

## 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