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 Nanocorcumin 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 Minoo 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)

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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 between25 - 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
Diadetic 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 intevention
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 Minoo 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 Minoo 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraeian
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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
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 nurition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Position

Associate professor

Latest degree

Ph.D.

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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