Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of curcumin on neurological complications of diabetes and HbA1c levels

Protocol summary

Study aim
Examine whether Curcumin can be effective in prevention, improving diabetes and its complications?

Design
Controlled clinical trial, community-based and pragmatic, with parallel, blind, and non-randomized groups. A statistical population of 120 patients with diabetic neuropathy. Patients are divided into two groups A and B. Group A consists of 60 patients as cases and group B 60 patients with diabetes as the control group. In a 3-month interval, group A receives 1 capsule of sinacurcumin every day. This is while group B patients receive placebo at similar intervals. At the end of the 3-month period, a laboratory profile similar to the beginning of the course are created for each patient. The results are examined, analyzed and compared

Settings and conduct
Mashhad University of Medical Sciences; Two-sided blinding (patients and researchers)

Participants/Inclusion and exclusion criteria
Entry requirements : Diabetes mellitus patients with neuropathy (gloves and socks) Age range of 70-18 years, sex and have at least five years of illness. The same type of medication used,Taking oral medicine and Controls for Diabetes.

Intervention groups
Intervention group: curcumin control group: placebo

Main outcome variables
1. HbA1C level 2. lab profile includes Lip a, BUN, U/A,Cr,FBS,TG,TC,HDL,LDL

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130811014330N6**
Registration date: **2019-06-02, 1398/03/12**
Registration timing: **retrospective**
Last update: **2019-06-02, 1398/03/12**
Update count: **0**

Registration date
2019-06-02, 1398/03/12

Registrant information

Name
Hamid Reza Rahimi

Name of organization / entity
Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Mashhad University of Medical Sciences,vice chancellor for research

Expected recruitment start date
2018-04-21, 1397/02/01

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of curcumin on neurological complications of diabetes and HbA1c levels

Public title
The effect of curcumin on neurological complications of diabetes and HbA1c levels

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetes mellitus with neuropathy (gloves and socks)
Age range of 70-18 years, at least five years with illness
The same type of medication used, Taking oral medicine

Exclusion criteria:

Age over 70 years and under 18 years Taking insulin

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

First, all patients with type 2 diabetes in 2 medical diagnostic laboratories in the city of Mashhad are examined. 120 patients who are diagnosed with diabetic neuropathy are selected. Patients are divided into two groups of 60 people. The first group is the case and the second group is the control. The first group is given a nano-curcumin capsule and second group, placebo capsules. During the course of the project, both groups are unaware of the type of capsule. Researchers are not aware of the type of capsule during the execution of the project. The appearance and taste of the main drug and the placebo are quite similar and are coded in a special way.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Knowledge and Health City – In the end of Shahid Fakouri Blvd (In front of Fakouri 94) – Mashhad - Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2018-06-27, 1397/04/06

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.091

Health conditions studied

1

Description of health condition studied

diabetic individuals with neuropathic disorders

ICD-10 code

E11.4

ICD-10 code description

Type 2 diabetes mellitus with neurological complications

Primary outcomes

1

Description

HbA1c

Timepoint

before and after using curcumin

Method of measurement

electrophoresis

Secondary outcomes

1

Description

2. The lab profile includes Lip a, BUN, U / A, Cr, FBS, TG, TC, HDL, LDL

Timepoint

Before and after using curcumin

Method of measurement

Spectrophotometry using an autoanalyzer

Intervention groups

1

Description

"Intervention :"This group receives 1 capsule of sinacurcumin every day.at the end of the 3-month period, a laboratory profile similar to the beginning of the course are created for each patient. The results are examined, analyzed and compared.

Category

Treatment - Drugs

2

Description

Control group: patients receive placebo at similar intervals.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Hamid Reza Rahimi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences,vice chancellor for research
Full name of responsible person
Dr Mohsen Tafaghodi
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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
Mashhad University of Medical Sciences,vice chancellor for research
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
Mashhad university of medical sciences
Full name of responsible person
Hamidreza Rahimi
Position
Associate professor
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data will be published in the form of a scientific paper upon completion of the project.

When the data will become available and for how long

Access to data and results is coincident with the publication of scientific articles in prestigious journals.

To whom data/document is available

Individual access is determined in accordance with the authorizations allowed by the publisher of the article.

Under which criteria data/document could be used

For this, researchers must contact the co-responding author of the article.

From where data/document is obtainable

co-responding author of the article.

What processes are involved for a request to access data/document

Communicate with the co-responding author of the article through the communication channels announced.

Comments