

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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

Country

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

Street address

Imam Reza hospital Sq, Mashhad

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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 sourceMashhad 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

Latest degree

Ph.D.

Other areas of specialty/work

General Practitioner

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr Hamidreza Rahimi & Dr.Zahra Mazlum khorasani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinologist and Metabolism Specialist

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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