

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study the effect of oral supplements “zinc and magnesium” on the control of Hemoglobin A1c in type II diabetic patients referred to Qom Shahid Beheshti hospital 2017-2018

Protocol summary

Study aim

Determination of the efficacy of supplemental zinc and magnesium alone and co-administration on the hemoglobin A1c control in type II diabetic patients

Design

Factorial clinical trial, with control group, triple-blind, randomized

Settings and conduct

First, patients with type II diabetes who are referred to the internal or endocrinology clinic of Shahid Beheshti Hospital are identified. Individuals are randomly divided into four groups. Individuals, in direct people and those who analyze the data, are unaware of the allocation of patients to different groups. The necessary tests performed through the laboratory of Shahid Beheshti Hospital and the rate of progression of diabetic neuropathy by The Michigan Neuropathy Instrument (MNSI) and Diagnostic Tool are used to check the progression of diabetic neuropathy every three months. Also, demographic information is completed by questionnaires.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Diabetic Type 2 Proven by Metabolic Indicators (FBS and 2HBP) - At least 3 years of diabetes history - aged over 20
Exit criteria: - Age over 60 - People with a history of myocardial infarction - People with hypermagnesemia - People with hyperzincemia - People with diabetic nephropathy - Insulin Consumers

Intervention groups

Intervention group1: Patient who receive oral zinc in the amount of 220 mg zinc sulfate, three days a week for six months. Intervention group 2: Patient receive magnesium oxide 250 mg three days a week for six months. Intervention group 3: Patient who receive magnesium oxide 250 mg three days a week and oral zinc as zinc sulfate at 220 mg three days a week for six months. Control group: The control group, which includes

Patient who receives placebo only for six months in addition to medication

Main outcome variables

Percentage of hemoglobin A1c in people with type 2 diabetes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190206042646N1**

Registration date: **2019-04-03, 1398/01/14**

Registration timing: **prospective**

Last update: **2019-04-03, 1398/01/14**

Update count: **0**

Registration date

2019-04-03, 1398/01/14

Registrant information

Name

Narges Kalhor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3770 2502

Email address

narges.kalhor1997@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-04, 1398/01/15

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effect of oral supplements “zinc and magnesium” on the control of Hemoglobin A1c in type II diabetic patients referred to Qom Shahid Beheshti hospital 2017-2018

Public title

Study the effect of oral supplements “zinc and magnesium” on diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Individual consent Diabetic Type 2 Proven by Metabolic Indicators (FBS and 2HBP) At least 3 years of diabetes history aged over 20

Exclusion criteria:

- Age over 60 Individual with a history of myocardial infarction Individual with hypermagnesemia Individual with hyperzincemia Patient with diabetic nephropathy Insulin Consumers

AgeFrom **20 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

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

Randomized

Randomization description

Random allocation method is based on blocking. Four blocks are used. The list of 24 blocks is written and randomly a number is selected and the sampling is continued based on it. ABCD, ABDC, ACBD, ACDB, ADBC, ADCB, BACD, BADC, BCAD, BCDA, BDAC, BDCA, CABD, CADB, CBAD, CBDA, CDAB, CDBA, DABC, DACB, DBCA, DBAC, DCAB, DCBA

Blinding (investigator's opinion)

Triple blinded

Blinding description

After dividing people into four different groups, patients are referred to the clerk and they train their medication and the correct way of taking them. Medications are pre-prepared and packaged out and packed in new ones as they are inserted on new packets of English letters, and the person who does not have direct intervention knows their meaning. Drug and placebo formulations of the same color The color and appearance of zinc,

magnesium, and placebo tablets are identical. Patients refer to the doctor after the assignment of the code in the group and the physician is unaware of their allocation to the different groups and only the secretary delivers the package of the patient package to the patient.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics committee of Qom University of Medical Science

Street address

Deputies Education & Research, No.83, Ave. 1/1, safashahr St., Qom

City

Qom

Province

Ghoum

Postal code

3716993456

Approval date

2019-01-01, 1397/10/11

Ethics committee reference number

IR.MUQ.REC.1397.147

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

Diabetes mellitus type2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes**1****Description**

Percentage of hemoglobin A1c in people with type 2 diabetes

Timepoint

Measurement of hemoglobin A1c at baseline, 3 and 6 months after the start of the intervention

Method of measurement

Biochemical analysis by reference laboratory

Secondary outcomes

1

Description

Peripheral neuropathy in patients with type 2 diabetes

Timepoint

Measurement of hemoglobin A1c at baseline, 3 and 6 months after the start of the intervention

Method of measurement

Michigan Neuropathy Survey Instrument(MNSI)

Intervention groups

1

Description

Intervention group1: People with type 2 diabetes, who in addition to medication, receive oral zinc in the amount of 220 mg zinc sulfate, three days a week for six months.

Category

Treatment - Drugs

2

Description

Intervention group 2: People with type 2 diabetes receive magnesium oxide 250 mg three days a week for six months in addition to medication.

Category

Treatment - Drugs

3

Description

Intervention group 3: People with type 2 diabetes, who in addition to medication, receive magnesium oxide 250 mg three days a week and oral zinc as zinc sulfate at 220 mg three days a week for six months.

Category

Treatment - Drugs

4

Description

Control group: The control group, which includes people with type 2 diabetes, who receive placebo only for six months in addition to medication.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Yaser Foroghi

Street address

Beheshti Blvd, Qom, Iran

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Ghous

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3719964797

Phone

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Email

bmc@muq.ac.ir

Web page address

<http://bmc.muq.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

No.83, Alley No. 4, Safashahr Street, Qom

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Web page address

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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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Reyhaneh Tabaraii

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Shahid Beheshti Hospital, Shahid Beheshti Blvd., Qom

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A Level or less

Other areas of specialty/work

General Practitioner

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

Ghous University of Medical Sciences

Full name of responsible person

Reyhaneh Tabaraii

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Postal code

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Email

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Person responsible for updating data**Contact****Name of organization / entity**

Ghous University of Medical Sciences

Full name of responsible person

Narges Kalhor

Position

Student

Latest degree**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

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

Title and more details about the data/document

All data can be shared after unidentifiable patients.

When the data will become available and for how long

Start the access period one year after the publishing results

To whom data/document is available

Researchers working in academic centers and pharmaceutical companies

Under which criteria data/document could be used

The use of data obtained for the purpose of directing and completing research projects is permissible.

From where data/document is obtainable

To receive the data, send your request to Narges Kalhor at narges.kalhor1997@gmail.com.

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

The request will be reviewed by the clinical trial responsible and the data will be sent to him after verifying the accuracy of the information received from the applicant.

Comments