Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 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
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target 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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Province
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Postal code
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
Ghoum 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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Fax
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Email
research@muq.ac.ir
Web page address
http://res.muq.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum 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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Person responsible for updating data

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Other areas of specialty/work
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narges.kalhor1997@gmail.com

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