Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Serum magnesium levels in type 2 diabetic patients and effect of magnesium supplement therapy in glycemic control and insulin resistance of these patients

Protocol summary

Study aim

Investigate the effect of serum magnesium level on insulin resistance and glycemic index in type 2 diabetic patients and evaluation of the efficacy and effectiveness of magnesium supplementation

Design

This double-blind, randomized (using Rand function of Excel software) clinical trial has an intervention and a parallel control group.

Settings and conduct

This study will be performed on diabetic patients referred to the outpatient clinic of Imam Reza (AS) Hospital in Tabriz. Patients will be randomly divided into intervention and control groups and will be examined and anthropometric measurements will be done. Blood samples will be taken before and after the intervention (Mg supplement/placebo). The data will be sent to the analyzer with numeral codes (blinded).

Participants/Inclusion and exclusion criteria

The study population will be selected among the patients referred to the outpatient clinic of Imam Reza (AS) Hospital in Tabriz. Inclusion criteria: 1. An adult patient with type 2 diabetes who has been diagnosed and treated for at least 1 year, using only oral medications. 2. The patient's HbA1c level should be between 7 to 10. Exclusion criteria: 1. Injecting insulin and taking Mg and Ca supplements, calcium channel blockers, and diuretics. 2. Renal failure, elevated liver enzymes, inflammatory disease, chronic diarrhea, and pregnancy.

Intervention groups

All patients will be examined, and their anthropometric criteria will be recorded. The intervention group will receive elemental magnesium in the form of 250 mg magnesium oxide tablets daily for 3 months, while the control group will receive a placebo. The medical regimen and antidiabetic drugs of any group of patients would not change.

Main outcome variables

Fasting blood sugar, fasting serum insulin, glycosylated hemoglobin, serum Mg level, HOMA-IR index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220504054735N1**
Registration date: **2022-11-15, 1401/08/24**
Registration timing: **retrospective**

Last update: **2022-11-15, 1401/08/24**
Update count: **0**

Registration date

2022-11-15, 1401/08/24

Registrant information

Name

Saba Habibzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3328 2003

Email address

habibzadeh.saba@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2022-08-06, 1401/05/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Serum magnesium levels in type 2 diabetic patients and effect of magnesium supplement therapy in glycemic control and insulin resistance of these patients

Public title
Magnesium supplement therapy in type2 diabetes
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
An adult patient with type 2 diabetes who has been diagnosed and treated for at least one year and been treated with oral medications only. The patient's HbA1c level should be between 7 to 10. The patient should be satisfied to participate in the study.
Exclusion criteria:
Injecting insulin and taking magnesium and calcium supplements, calcium channel blockers, and diuretics. Renal failure, elevated liver enzymes, inflammatory disease, chronic diarrhea, and pregnancy. Participants should not have been admitted to another clinical trial at the same time.
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
All patients (N=60) who meet the conditions for entering the study, after obtaining personal consent and justifying the objectives of the study, will receive one of the two interventions (supplement or placebo) in the clinic based on the randomized list previously provided to the researcher. The randomization of patients will be in the form of blocks of 4 patients prepared by the website 'www.sealedenvelope.com' in which 2 patients are assigned to the intervention group and 2 others to the control group. Finally, 30 patients will enter the intervention group, and 30 will enter the control group. The researcher will not make any changes to the randomized list of people.
Blinding (investigator's opinion)
Double blinded
Blinding description
The participants would be blinded using a placebo. In addition, data would be sent to the analyzer by using numeral codes, so the analyzer would be unaware of groups. (analyzer blinding)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Faculty of Medicine, next to Imam Reza hospital, Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2022-05-11, 1401/02/21
Ethics committee reference number
IR.TBZMED.REC.1401.174

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Insulin resistance
Timepoint
Measurement of blood factors will be done twice (one at the beginning, before the start of the intervention, and the other three months later).
Method of measurement
Blood tests

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive elemental magnesium in the form of 250 mg magnesium oxide tablets daily for three months
Category
Rehabilitation

2

Description
Control group: Taking placebo, in the form of tablet, once a day, for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital
Full name of responsible person
Saba Habibzadeh
Street address
Golgasht street
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5166614756
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Fax
+98 41 3335 2073
Email
imamreza@tbzmed.ac.ir
Web page address
https://imamreza.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Daruosh Savadi oskouei
Street address
Next to Imam Reza hospital, Golgasht street
City
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East Azarbaijan
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5166614766
Phone
+98 41 3337 6923
Fax
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Email
info.medfac@tbzmed.ac.ir
Web page address
https://medfac.tbzmed.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Saba Habibzadeh
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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5th floor, Arghavan building, No.8, 4th west Ave., Besat Alley, Tavanir Blvd.
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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
Yes - There is 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
Title and more details about the data/document
For ethical reasons, we have no plan to publish participants' data. The informed consent form will be provided to participants. Descriptions of the protocol and method of analysis will be mentioned in the text of the article.
When the data will become available and for how long
The access period starts from the time the results and article are published.
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The data will only be available for further studies on similar topics.
From where data/document is obtainable
To receive information and data about this study, please contact the following e-mail: habibzadeh.saba@gmail.com
What processes are involved for a request to access data/document
Your request will be answered within two days and the requested documents will be sent in the shortest possible time.
Comments