Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

The effectiveness of oral magnesium administration on blood sugar, glycosylated hemoglobin, and lipid profile parameters of patients with type 1 diabetes

Protocol summary

Study aim

The effectiveness of oral magnesium administration on glycemic and metabolic control of patients with type 1 diabetes

Design

Randomized(By assigning coded envelopes), Controlled, double-blinding clinical trial, with the parallel groups, Phase 3 on 120 patients

Settings and conduct

In this randomized double-blind clinical trial study, 120 eligible patients, referring to Imam Hossein Hospital of Isfahan, will be included in the study and will be randomly divided into two groups (each group in two sections of diabetic patients with and without overweight and obesity). Oral magnesium sachets are prescribed for the intervention group and the placebo for the control group. The intervention will be performed in such a way that the patient, the researcher, and the statistical analyst will have no knowledge of the type of intervention. Then the blood parameters, lipidemia, and body mass index of the patients before and after the intervention will be compared between the groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study include having type 1 diabetes, age range from 6 to 18 years, and having consent to participate in the study; Exclusion criteria include having a history of sensitivity to magnesium compounds, suffering from chronic diseases, using special drugs other than insulin, and using calcium-containing compounds.

Intervention groups

Control group: For patients in this group, the placebo (in the form of sachets) is prescribed daily for 6 months. Intervention group: For patients in this group, oral magnesium sachets are prescribed daily according to the standard instructions(according to the age of the child), for 6 months.

Main outcome variables

Blood sugar; Glycosylated hemoglobin; High-density lipoprotein cholesterol (HDL); Low-density lipoprotein cholesterol (LDL); Body mass index(BMI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056231N1**
Registration date: **2022-12-18, 1401/09/27**
Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**
Update count: **0**

Registration date

2022-12-18, 1401/09/27

Registrant information

Name

Neda Mostofizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3386 5016

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nmostofizadeh@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of oral magnesium administration on blood sugar, glycosylated hemoglobin, and lipid profile parameters of patients with type 1 diabetes

Public title

The effect of oral magnesium on glycemic and metabolic control in patients with type 1 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having type 1 diabetes Age range from 6 to 18 years

Exclusion criteria:

History of sensitivity to magnesium compounds Suffering from chronic diseases Use of special medicine other than insulin Use of compounds containing calcium

Age

From **6 years** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

First, 60 eligible to enter study patients with type 1 diabetes, who are overweight or obese, are selected non-randomly. Then the letter A is written on 30 leaves and the letter B is written on 30 leaves and each is placed in an envelope. Then each patient is asked to choose one envelope from among the envelopes. Then,60 eligible to enter study patients with type 1 diabetes, who are not overweight or obese are selected non-randomly. Then the letter C is written on 30 leaves and the letter D is written on 30 leaves and each is placed in an envelope. Then each patient is asked to choose one envelope from among the envelopes. In this way, according to the envelope selected without the researcher's intervention, the patients will be randomly assigned to one of the intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, magnesium sulfate and the placebo are prepared by the pharmacist in the same shape, size, and color and will be marked with A and B labels and provided to the researcher. He/She also prescribe them without knowing the type of each medicine. Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Ethics committee , Isfahan University of Medical Sciences, Hezarjarib Blvd, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2022-10-24, 1401/08/02

Ethics committee reference number

IR.MUI.MED.REC.1401.274

Health conditions studied

1

Description of health condition studied

Type 1 diabetes

ICD-10 code

E10.9

ICD-10 code description

Type 1 diabetes mellitus without complications

Primary outcomes

1

Description

Blood sugar

Timepoint

Before intervention and 6 months after taking magnesium supplement

Method of measurement

Blood test

2

Description
Glycosylated hemoglobin
Timepoint
Before intervention and 6 months after taking magnesium supplement
Method of measurement
Blood test

3

Description
High-density lipoprotein cholesterol (HDL)
Timepoint
Before intervention and 6 months after taking magnesium supplement
Method of measurement
Blood test

4

Description
Low-density lipoprotein cholesterol (LDL)
Timepoint
Before intervention and 6 months after taking magnesium supplement
Method of measurement
Blood test

5

Description
Body mass index(BMI)
Timepoint
Before intervention and 6 months after taking magnesium supplement
Method of measurement
Meters and Clinic scales

Secondary outcomes

empty

Intervention groups

1

Description
Control group: For patients in this group, one gram sachets of placebo (Isfahan Faculty of Pharmacy) are prescribed for 6 months according to the standard instructions (according to the child's age). In this way, it will be prescribed three days a week for children 6-8 years old, five days a week for children 9-13 years old, and seven days a week (every day) for children 14 years old and above.
Category
Placebo

2

Description
Intervention group: For patients in this group, 1 gr sachets of oral magnesium (Bonyan Salamat Kasra Company) containing 300 mg of pure magnesium are prescribed for 6 months according to the standard instructions (according to the child's age). In this way, it will be prescribed three days a week for children 6-8 years old, five days a week for children 9-13 years old, and seven days a week (every day) for children 14 years old and above.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imamhosein Hospital of Isfahan
Full name of responsible person
Seyed Ebrahim Tababtabayipoor
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Isfahan University of Medical SciencesVice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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dean@med.mui.ac.ir
Web page address
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Seyed Ebrahim Tabatabayipoor
Position
Fellowship
Latest degree
Specialist
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Person responsible for updating data

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Position
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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
Undecided - It is not yet known if there will be 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