Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Sep 2026

A comparative study on the effect of oral Magnesium supplementation versus placebo on Hypertension in patients with type 2 diabetes

Protocol summary

Study aim
Randomized allocation of patients with type 2 diabetes and hypertension to standard treatment with or without oral magnesium, with measurement of systolic and diastolic blood pressure

Design
A total of 30 participants per group will be enrolled consecutively based on eligibility criteria. Sample size was calculated as 26 per group using G*Power 3.1.9.7 (effect size = 0.8, 80% power, 95% confidence) and increased to 30 per group to account for potential dropouts. Participants will be randomly assigned to receive either oral magnesium supplementation or placebo)

Settings and conduct
Patients with type 2 diabetes and hypertension attending the Internal Medicine Clinic of LOGHMAN Hakim Hospital (2025-2026) will be enrolled. Those on Valsartan/Amlodipine and insulin analogs will, after informed consent, be randomly assigned to standard treatment with or without oral magnesium. Follow-up occurs at weeks 4 and 8, with blood pressure measured using a manual manometer

Participants/Inclusion and exclusion criteria
Patients with type 2 diabetes and hypertension without prior gastrointestinal complications

Intervention groups
Patients aged 30 to 70 years with type 2 diabetes (diagnosed according to ADA criteria) who are treated with insulin analogs and who also have high blood pressure and are treated with valsartan/amlodipine, if they do not meet the exclusion criteria will be included in the study after obtaining informed written consent. After randomization, patients are assigned to two groups receiving oral magnesium citrate and placebo, and their blood pressure is assessed at baseline, four and eight weeks later.

Main outcome variables
Systolic blood pressure; Diastolic blood pressure; Fasting blood glucose; HbA1c; Serum magnesium; Adverse events (diarrhea, hypotension, arrhythmia)

General information

Reason for update

Acronym
HTN

IRCT registration information
IRCT registration number: **IRCT20230522058258N2**
Registration date: **2026-01-02, 1404/10/12**
Registration timing: **prospective**

Last update: **2026-01-02, 1404/10/12**
Update count: **0**

Registration date
2026-01-02, 1404/10/12

Registrant information

Name
Arezoo Ranjbar Arani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 4427 0497

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arezoo.ranjbar@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-04, 1404/10/14

Expected recruitment end date
2026-05-04, 1405/02/14

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on the effect of oral Magnesium supplementation versus placebo on Hypertension in patients with type 2 diabetes

Public title

The effect of oral Magnesium supplementation on Hypertension in patients with type 2 diabetes

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of type 2 diabetes mellitus according to the American Diabetes Association (ADA) criteria Controlled or uncontrolled hypertension under pharmacological treatment Provision of written informed consent Presence of severe renal disease (eGFR < 30 ml/min/1.73 m^2) Presence of heart failure classified as New York Heart Association (NYHA) class III or IV History of magnesium supplementation or use of medications affecting serum magnesium levels Systolic blood pressure < 90 mmHg or blood pressure ≥ 160/90 mmHg at baseline requiring therapeutic intervention or medication adjustment Pregnancy Presence of gastrointestinal disorders that impair magnesium absorption

Exclusion criteria:

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The steps of random assignment of patients to two experimental and control groups will be as follows: 1- Creating a random sequence of Random Sequence Generation will be done in the form of simple randomization and through the preparation and shuffling of cards. So that a number of cards will be prepared as the first group and the same number of cards will be prepared for the next groups. Then, by removing them, a card is taken out and its assignment is registered, and that card is returned to the other cards. Then the cards are dealt again and another card is drawn. This process will continue until reaching a random sequence according to the sample size. 2- Random allocation concealment will be done by placing the aforementioned cards inside Sequentially Numbered Sealed Opaque Envelopes (SNOSE). 3- People from the research team who are responsible for the above steps will not enter the other steps of the research, especially the examination of people in terms of the dependent variable.

Blinding (investigator's opinion)

Single blinded

Blinding description

either the intervention group (magnesium supplementation) or the control group (placebo). The magnesium supplement and placebo are identical in appearance and packaging and are coded accordingly. Investigators and healthcare personnel are aware of group allocation and are responsible for administering the intervention and patient follow-up. Access to the allocation codes by the Data Safety and Monitoring Committee, if established, will be permitted only when required for safety reasons. All participants provide written informed consent prior to enrollment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sahid Beheshti University of Medical Sciences

Street address

Loqman Hakim hospital - special St. - Lashgar intersection

City

تهران

Province

Tehran

Postal code

1333635445

Approval date

2025-12-09, 1404/09/18

Ethics committee reference number

IR.SBMU.MSP.REC.1404.602

Health conditions studied

1

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description
Systolic Blood Pressure
Timepoint
Before the intervention and 1 and 2 months after the intervention
Method of measurement
Sphygmomanometer

2

Description
Diastolic blood pressure
Timepoint
Before the intervention and 1 and 2 months after the intervention
Method of measurement
Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: They are treated with 300 mg of oral magnesium daily for 2 months
Category
Treatment - Drugs

2

Description
Control group: they are treated with a placebo for 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Arezoo Ranjbar Arani
Street address
Loghman Hakim Hospital, Kamali St., South Kargar Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Yaman St, Velenjak St, Shahid Chamran Highway
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Postal code
1985717443
Phone
+98 21 2243 9770
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arezoo Ranjbar Arani
Position
Associate professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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 variables and information about participants can be shared after de-identifying people
When the data will become available and for how long
At the time of publication
To whom data/document is available
All treatment staff, researchers and people who intend to verify the data will be able to access the data
Under which criteria data/document could be used
If the source is mentioned, the data will be made available to the requesters
From where data/document is obtainable
Refer to the organizers of the plan or to Loghman Hakim Hospital in Tehran
What processes are involved for a request to access data/document
The request is made by email or phone and the information will be sent in the form of e-mail
Comments