

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)

Phone

+98 21 4427 0497

Email address

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 m²) 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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1333625445

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drranjbar.ar@gmail.com

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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1985717443

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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

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

Specialist

Other areas of specialty/work

Internal Medicine

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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