

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of oral magnesium supplementation and placebo on cardio metabolic markers in prediabetes subjects: a randomized, double blinded clinical trial

Protocol summary

Study aim

Effect of oral magnesium supplementation on cardio metabolic markers in people with prediabetes

Design

Two arm parallel groups (Case and Control) randomised trial, consisting of 70 patients with blinded postoperative care and outcome assessment.

Settings and conduct

This study was performed on patients referring to Endocrine and Metabolism Research Center affiliated to Isfahan University of Medical Sciences. A questionnaire is given to selected subjects who have entry criteria. Before the intervention, a blood sample is taken from the patient and sent to the laboratory of the center. The patients' anthropometric indices data is also collected. The findings and results of the test are recorded in the patient file and archived with the questionnaire. Patients are randomly distribute in two groups of oral magnesium and placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Prediabetes condition; Age >18 and <65; Serum magnesium level $\leq 2\text{mg/dL}$; GFR>60mL/min; Blood Pressure lower than 140/90 mmHg. Non-inclusion criteria: smoking; Chronic Diarrhea; Consume diuretics; Pregnancy; Liver diseases; Chronic diseases; Consume magnesium supplements in last 6 months.

Intervention groups

Intervention group: 320 mg elemental magnesium pill, daily, for 12 weeks. Control group: Placebo daily for 12 weeks

Main outcome variables

Fasting blood glucose; HbA1c; Lipid profile; Uric acid; Fasting serum insulin; CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181226042129N1**

Registration date: **2019-04-01, 1398/01/12**

Registration timing: **retrospective**

Last update: **2019-04-01, 1398/01/12**

Update count: **0**

Registration date

2019-04-01, 1398/01/12

Registrant information

Name

Golshan Taghipour Borujeni

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3337 7664

Email address

g.taghipour@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral magnesium supplementation and placebo on cardio metabolic markers in prediabetes subjects: a randomized, double blinded clinical trial

Public title

Effect of oral magnesium supplementation on cardio metabolic markers in people at risk of diabetes

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

prediabetes condition not consuming magnesium supplements in last 6 months and serum magnesium level less than 2mg/dL GFR > 60mL/min Blood pressure less than 140 / 90 mmHg

Exclusion criteria:

Pregnancy Chronic diseases Liver diseases Chronic diarrhea Smoking Consume diuretics Consuming anti hypertensive drugs

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization with blocks of size 2

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blind approach will be used and both investigator and participants are blinded regarding the treatments

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

Isfahan University of Medical Sciences, Hezar Jarib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.MUI.MED.REC.1397.252

Health conditions studied

1

Description of health condition studied

Prediabetes

ICD-10 code

E12

ICD-10 code description

Malnutrition-related diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Day 0 and day 120

Method of measurement

Lab test

2

Description

HbA1c

Timepoint

Day 0 and 120

Method of measurement

Lab test

3

Description

Lipid profile

Timepoint

Day 0 and 120

Method of measurement

Lab test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To these patients, oral magnesium tablets (320 mg) are given daily for a period of twelve weeks. The magnesium pill is the product of the Jalinus Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: To these patients, placebo tablets are given daily for twelve weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Endocrine and Metabolism Research Center

Full name of responsible person

Leila Mirzaei

Street address

Khorram street, Jomhori Eslami sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Ashraf Aminorroaya

Street address

Hezar Jarib Street, Isfahan University of Medical Sciences

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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

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

Golshan Taghipour Borujeni

Position

Subspecialist Resident

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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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