

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Clinical trial of the effect of magnesium supplementation compared with the placebo on gene expression related to insulin and lipid in women with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of magnesium supplementation on gene expression related to insulin and lipid in patients of gestational diabetes.

Design

Design: Randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive magnesium supplements (n=20) or placebo (n=20).

Settings and conduct

Population and sample size: Among patients with gestational diabetes referred to gynecology Clinic affiliated to Arak University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes; aged 18 to 40 years. Exclusion criteria: Taking magnesium supplements within the past 3 months, needing to insulin therapy during the intervention, pre-eclampsia, eclampsia, hypo and hyperthyroidism, and smokers.

Intervention groups

Intervention: Patients will be assigned into two groups to receive magnesium (n=20) or placebo (n=20). Magnesium and placebo capsules are similar in shape and size. At the beginning and end of the intervention: 6 weeks.

Main outcome variables

Outcomes: Gene expression related to insulin (primary outcomes) and gene expression related to lipid (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201704235623N111**

Registration date: **2017-04-29, 1396/02/09**

Registration timing: **retrospective**

Last update: **2019-09-21, 1398/06/30**

Update count: **1**

Registration date

2017-04-29, 1396/02/09

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2017-03-07, 1395/12/17

Expected recruitment end date

2017-04-06, 1396/01/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of magnesium supplementation compared with the placebo on gene expression related to insulin and lipid in women with gestational diabetes

Public title
Effect of supplementation in treatment of women with gestational diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with gestational diabetes Aged 18 to 40 years
Exclusion criteria:
Taking magnesium supplements within the past 3 months Needing to insulin therapy during the intervention Pre-eclampsia Eclampsia Hypo and hyperthyroidism Smokers

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
At study baseline and after balanced blocked randomisation, subjects will be allocated into two groups to take either magnesium supplements (n=20) or placebo (n=20). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo
Used

Assignment
Parallel

Other design features
Randomization will be done by the use of computer-generated random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

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Province

Markazi

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3814113634

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.ARAKMU.REC.1395.440

Health conditions studied

1

Description of health condition studied

Gestational diabetes

ICD-10 code

O24.9

ICD-10 code description

Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description

Expressed levels of PPAR-γ

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

2

Description

Expressed levels of GLUT-1

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

Secondary outcomes

1

Description

Expressed levels of LDLR gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

2**Description**

Expressed levels of Lp(a) gene

Timepoint

At the beginning of the study and after 6 weeks of intervention

Method of measurement

PCR

Intervention groups**1****Description**

Intervention group: Magnesium supplements (21st Century, Arizona, USA), 250 mg, daily, for 6 weeks orally.

Category

Treatment - Drugs

2**Description**

Control group: Placebo capsule, daily for 6 weeks orally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kosar Clinic

Full name of responsible person

Mehri Jamilian

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Arak University of

Medical Sciences

Full name of responsible person

Mohammad Rafiee

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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

Vice chancellor for research, Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Mehri Jamilian

Position

Gynecologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

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