

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Clinical trial of the effect of magnesium supplementation compared with the placebo on gene expression related to inflammation and pregnancy outcomes in women with gestational diabetes mellitus

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of magnesium supplementation on gene expression related to inflammation and pregnancy outcomes in patients with gestational diabetes mellitus.

Design

Study 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 supplement (n=20) or placebo (n=20).

Settings and conduct

Among patients with gestational diabetes referred to Akbarabadi Clinic affiliated to Iran University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Intervention group: 250 mg magnesium (21st Century Pharmaceutical Company, Arizona, USA), daily for 6 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N25**

Registration date: **2017-12-29, 1396/10/08**

Registration timing: **retrospective**

Last update: **2019-09-13, 1398/06/22**

Update count: **1**

Registration date

2017-12-29, 1396/10/08

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5546 3378

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ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-16, 1396/08/25

Expected recruitment end date

2017-11-30, 1396/09/09

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 inflammation and pregnancy outcomes in women with gestational diabetes mellitus

Public title

Effect of magnesium supplementation in treatment of gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: Patients with gestational diabetes mellitus. Individuals aged 18 to 40 years.

Exclusion criteria:

Taking magnesium and antioxidants supplements 3 months before the intervention
Needing insulin therapy
Pre-eclampsia
Eclampsia
Hypo and hyperthyroidism
Smokers

Age

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

Gender

Female

Phase

2

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 randomisation, subjects will be allocated into two groups to receive supplement or placebo. 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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical

Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-11-15, 1396/08/24

Ethics committee reference number

IR.IUMS.FMD.REC.1396.9411290018

Health conditions studied

1

Description of health condition studied

Gestational diabetes mellitus

ICD-10 code

O24.9

ICD-10 code description

Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Expressed levels of TNF-a gene

Timepoint

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

Method of measurement

PCR

2

Description

Expressed levels of IL-1 gene

Timepoint

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

Method of measurement

PCR

3

Description

Expressed levels of IL-8 gene

Timepoint

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

Method of measurement

PCR

Secondary outcomes

1

Description

Expressed levels of TGF-B gene

Timepoint

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

Method of measurement

PCR

2

Description

Expressed levels of VEGF gene

Timepoint

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

Method of measurement

PCR

3

Description

Newborn's head circumference

Timepoint

Delivery time

Method of measurement

Tape

4

Description

Newborn's weight

Timepoint

Delivery time

Method of measurement

Scale

5

Description

Polyhydramnios

Timepoint

End-of-trial

Method of measurement

Sonography

6

Description

Newborn length

Timepoint

The first 24 h after birth

Method of measurement

Girth measuring tape

Intervention groups

1

Description

Intervention group: 250 mg magnesium (21st Century Pharmaceutical Company, Arizona, USA), daily for 6

weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Clinic

Full name of responsible person

Shahnaz Ahmadi

Street address

Akbarabadi Hospital, Mowlavi Street, Tehran

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Tehran

Province

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1168743514

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ahmadi.shahnaz@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi

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Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran

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1168743514

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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

Iran 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

Kashan
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Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutritionist
Latest degree
Ph.D.
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Person responsible for updating data

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available