

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Clinical trial of the effect of multi mineral-vitamin D supplementation compared with the placebo on metabolic profiles in women with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of multi mineral-vitamin D supplementation on metabolic profiles in patients of gestational diabetes.

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive supplements (n=30) or placebo (n=30).

Settings and conduct

Among patients with gestational diabetes referred to Akbarabadi Clinic affiliated to Iran University of Medical Sciences, 60 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, zinc, calcium and/or vitamin D supplements during the last 3 months, taking insulin, placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism, smokers, kidney or liver diseases.

Intervention groups

Intervention: Patients will be assigned into two groups to receive multi mineral-vitamin D (n=30) or placebo (n=30). Multi mineral-vitamin D and placebos capsules are similar in shape and size.

Main outcome variables

Outcomes: Glycemic control (primary outcomes) and lipid profiles (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201706045623N116**

Registration date: **2017-06-18, 1396/03/28**

Registration timing: **retrospective**

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

Update count: **1**

Registration date

2017-06-18, 1396/03/28

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, Iran University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-05-15, 1396/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of multi mineral-vitamin D supplementation compared with the placebo on metabolic profiles 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:
Intake of magnesium, zinc, calcium and/or vitamin D supplements during the last 3 months Taking insulin Placenta abruption 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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
To decrease potential confounding effects, after balanced blocked randomisation, all participants will have allocated into two treatment groups to take either supplements or placebo. Randomization will be done by the use of computer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed.

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

City
Tehran

Province
Tehran

Postal code
14665-354

Approval date
2017-05-04, 1396/02/14

Ethics committee reference number
IR.IUMS.REC.1396.53499450411

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

Insulin

Timepoint

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

Method of measurement

Elisa kit

2

Description

Insulin resistance

Timepoint

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

Method of measurement

Using HOMA formula

Secondary outcomes

1

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

Total cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

3

Description
HDL-cholesterol
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
LDL
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
VLDL
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
FPG
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Intervention group: Multi mineral-vitamin D supplements (Vitane, Wolfratshausen, Germany), 800 mg calcium, 200 mg magnesium, 8 mg zinc, 400 IU vitamin D3, 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
Akbarabadi Clinic
Full name of responsible person
Maryam Karamali
Street address
Akbarabadi Hospital, Mowlavi Street, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
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Phone
+98 21 8805 2248
Email
moosavi-sa@iums.ac.ir
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, 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

Person responsible for general 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