Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Clinical trial of the effect of combined vitamin E and zinc supplementation compared with the placebo on metabolic profiles and gene expression related to insulin and lipid in women with gestational diabetes mellitus

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of combined vitamin E and zinc supplementation on metabolic profiles and gene expression related to insulin and lipid 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 combined vitamin E and zinc supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with gestational diabetes referred to Naghavi gynecology Clinic affiliated to Kashan 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. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 6 weeks after the intervention. At the beginning and the end of the intervention: 6 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with gestational diabetes aged 18 to 40 years. Inclusion criteria: Patients with gestational diabetes aged 18 to 40 years. Exclusion criteria: Taking zinc and vitamin E supplements 3 months before the intervention, insulin therapy required during the intervention, pre-eclampsia, eclampsia, hypo and hyperthyroidism.

Intervention groups

Intervention group: 400 IU vitamin E (Zahravi, Tabriz, Iran) and 30 mg elemental zinc (Donyaye Behdasht, Tehran, Iran) daily for 6 weeks orally. Control group: Placebo (Barij Essence, Kashan, Iran), daily for 6 weeks orally.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N26**
Registration date: **2018-01-07, 1396/10/17**
Registration timing: **retrospective**

Last update: **2019-09-22, 1398/06/31**
Update count: **1**

Registration date

2018-01-07, 1396/10/17

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5546 3378

Email address

ostadmohammadi-vr@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-27, 1396/09/06

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial of the effect of combined vitamin E and zinc supplementation compared with the placebo on metabolic profiles and gene expression related to insulin and lipid in women with gestational diabetes mellitus

Public title
Effect of combined vitamin E and zinc supplementation in treatment of gestational diabetes mellitus
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Patients with gestational diabetes mellitus. Individuals aged 18 to 40 years.
Exclusion criteria:
Exclusion criteria: Taking zinc and vitamin E supplements 3 months before the intervention Insulin therapy required during the intervention Pre-eclampsia Eclampsia Hypo and hyperthyroidism
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 be 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
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 National Institute for Medical Research Development of Iran (NIMAD)
Street address
National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran
City
Tehran
Province
Tehran
Postal code
1419693111
Approval date
2017-11-26, 1396/09/05
Ethics committee reference number
IR.NIMAD.REC.1396.133

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
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
Calculation using HOMA formula

Secondary outcomes

1

Description

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

HDL

Timepoint

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

Method of measurement

Enzymatic kit

3

Description

Triglycerides

Timepoint

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

Method of measurement

Enzymatic kit

4

Description

Expressed levels of PPAR-γ gene

Timepoint

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

Method of measurement

PCR

5

Description

LDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

6

Description

VLDL-cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

7

Description

Expressed levels of LDLR gene

Timepoint

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

Method of measurement

PCR

Intervention groups

1

Description

Intervention group: 400 IU vitamin E (Zahravi, Tabriz, Iran) and 30 mg elemental zinc (Donyaye Behdasht, Tehran, Iran) 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

Naghavi gynecology Clinic

Full name of responsible person

Mansoreh Samimi

Street address

Shahid Rajaee Avenue, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 4446 0180

Fax

Email

samimi_m@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development of Iran (NIMAD)

Full name of responsible person

Dr. Reza Malekzadeh

Street address

National Institute for Medical Research Development of Iran, Fatemi Avenue, Tehran

City

Tehran

Province

Tehran
Postal code
1419693111
Phone
+98 21 6693 8037
Email
malek@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
National Institute for Medical Research Development of Iran (NIMAD)
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
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
Nutritionist
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Fax
Email
asemi_z@kaums.ac.ir
Web page address

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