Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of selenium and probiotics co-supplementation on on pregnancy outcomes, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of zinc and vitamin E supplementation on pregnancy outcomes, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation 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 probiotics and selenium supplement (n=30) or placebo (n=30).

Settings and conduct

Among patients with GDM referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes will be 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 mellitus aged 18 to 40 years. Exclusion criteria: Taking any supplements before the intervention.

Intervention groups

Intervention group: Combined probiotic, including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Bifidobacterium langum, 2×109 Bifidobacterium lactis daily, and selenium supplements (Webber Naturals, Canada), 200 µg, daily, for 6 weeks orally. Control group: Probiotic and selenium placebo capsules (Barij essence, Kashan, Iran), daily, for 6 weeks orally.

Main outcome variables

Outcomes: Markers of insulin metabolism (primary outcomes) and lipid profiles, 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: **IRCT20170513033941N55**
Registration date: **2019-04-05, 1398/01/16**
Registration timing: **retrospective**

Last update: **2019-04-05, 1398/01/16**
Update count: **0**

Registration date

2019-04-05, 1398/01/16

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

2019-01-23, 1397/11/03

Expected recruitment end date
2019-02-22, 1397/12/03
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of selenium and probiotics co-supplementation on on pregnancy outcomes, inflammatory factors, oxidative stress biomarkers and gene expression related to inflammation in women with gestational diabetes

Public title
The effects of selenium and probiotics co-supplementation in the treatment of women with gestational diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with gestational diabetes mellitus. Individuals aged 18 to 40 years.
Exclusion criteria:
overt diabetes mellitus Taking any supplements before the intervention Unwillingness to cooperate.
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, all participants will have stratified randomization according to BMI (<25 and ≥25 kg/m2) and age (<30 and ≥30 y). Then, participants in each block will be randomly 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. Another person at the Kosar clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences
City
Arak
Province
Markazi
Postal code
1771844351
Approval date
2019-01-22, 1397/11/02
Ethics committee reference number
IR.ARAKMU.REC.1397.301

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
Hs-CRP
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Elisa kit

Secondary outcomes

1

Description
Nitric oxide

Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

2

Description
Malondialdehyde
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

3

Description
Glutathione
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
Spectrophotometry

4

Description
Total antioxidant capacity
Timepoint
Total antioxidant capacity
Method of measurement
Spectrophotometry

5

Description
Expressed levels of TNF gene
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
PCR

6

Description
Expressed levels of TGF-β gene
Timepoint
At the beginning of the study and after 6 weeks of intervention
Method of measurement
PCR

7

Description
Newborn's head circumference
Timepoint
Delivery time
Method of measurement
Tape

8

Description
Newborn's weight
Timepoint
Delivery time
Method of measurement
Scale

9

Description
Polyhydramnios
Timepoint
End-of-trial
Method of measurement
Sonography

10

Description
Newborn length
Timepoint
The first 24 h after birth
Method of measurement
Girth measuring tape

Intervention groups

1

Description
Intervention group: Combined probiotic, including 2×109 Lactobacillus acidophilus, 2×109 Bifidobacterium bifidum, 2×109 Bifidobacterium langum, 2×109 Bifidobacterium lactis daily, and selenium supplements (Webber Naturals, Canada), 200 µg, 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
Kosar Clinic
Full name of responsible person
Maryam Shokrpour
Street address
Emam Khomeyni Avenue, Arak
City
Arak
Province

Markazi
Postal code
8115187159
Phone
+98 31 4446 0180
Email
Shokrpour.m@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Mohammad Arjmandzadegan
Street address
Sardasht Avenue, Vice chancellor for research, Arak University of Medical Sciences
City
Arak
Province
Markazi
Postal code
1771844351
Phone
+98 31 5546 3378
Email
Arjmandzadegan.m@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
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
PhD of Nutrition
Latest degree
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Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
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
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province

Isfehan

Postal code

1771844351

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