

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Clinical trial of the effect of combined probiotic and 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 combined probiotic and vitamin D supplementation on gene expression related to insulin and lipid in patients of gestational diabetes.

Design

Study design: Parallel double-blind (both patients and researchers) clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Among patients with gestational diabetes referred to Kosar gynecology Clinic affiliated to Arak University of Medical Sciences, 90 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 vitamin D, probiotic and/or symbiotic during the last 3 months prior to the intervention, insulin therapy during the intervention, pre-eclampsia, eclampsia, hypo and hyperthyroidism, smokers.

Intervention groups

Intervention: Patients will be assigned into three groups to receive combined probiotic and vitamin D (n=30) or probiotic (n=30) or placebo (n=30). Probiotic, vitamin D and placebos capsules are similar in shape and size.

Main outcome variables

Outcomes: Insulin metabolism (primary outcomes) and lipid profiles, biomarkers of inflammation and oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201706075623N119**

Registration date: **2017-06-09, 1396/03/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-23, 1398/07/01**

Update count: **1**

Registration date

2017-06-09, 1396/03/19

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

2017-05-16, 1396/02/26

Expected recruitment end date

2017-07-17, 1396/04/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of combined probiotic and 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:

Pre-eclampsia Eclampsia Hypo and hyperthyroidism
Smokers Taking vitamin D, probiotic and/or symbiotic supplements during the last 3 months prior to the intervention Insulin therapy during the intervention

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: **90**

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.

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

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

City

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Province

Markazi

Postal code

3814113634

Approval date

2017-05-15, 1396/02/25

Ethics committee reference number

IR.ARAKMU.REC.1396.26

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**

Total cholesterol

Timepoint

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

Method of measurement

Enzymatic kit

2

Description

Triglycerides

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

Total antioxidant capacity

Timepoint

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

Method of measurement

Spectrophotometry

5

Description

Total glutathione

Timepoint

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

Method of measurement

Spectrophotometry

6

Description

VLDL

Timepoint

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

Method of measurement

Enzymatic kit

7

Description

LDL

Timepoint

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

Method of measurement

Enzymatic kit

8

Description

hs-CRP

Timepoint

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

Method of measurement

Elisa kit

9

Description

Malondialdehyde

Timepoint

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

Method of measurement

Spectrophotometry

10

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

11

Description

Fasting plasma glucose

Timepoint

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

Method of measurement

Enzymatic kit

12

Description

Newborn's head circumference

Timepoint

Delivery time

Method of measurement

Tape

13

Description

Polyhydramnios

Timepoint

End-of-trial

Method of measurement

Sonographic

14

Description

Newborn's bilirubin

Timepoint

Delivery time

Method of measurement

Enzymatic kit

15

Description

Apgar score

Timepoint

Delivery time

Method of measurement

Clinical observation

16

Description

Newborns' hypoglycemia

Timepoint

After delivery

Method of measurement

Enzymatic kit

17

Description

Preterm delivery

Timepoint

After delivery

Method of measurement

Medical record

18

Description

Maternal pre-eclampsia

Timepoint

After delivery

Method of measurement

Medical record

19

Description

Maternal hospitalization

Timepoint

After delivery

Method of measurement

Medical record

20

Description

Newborns' hospitalization

Timepoint

After delivery

Method of measurement

Medical record

21

Description

Newborns' length

Timepoint

After delivery

Method of measurement

Tape

Intervention groups

1

Description

Intervention group: Probiotic supplements (Zist Takhmir, Tehran, Iran), 2×10⁹ Lactobacillus acidophilus, 2×10⁹ Bifidobacterium bifidum, 2×10⁹ Lactobacillus reuteri, 2×10⁹ Lactobacillus fermentum, daily, for 6 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Probiotic and vitamin D placebos capsule (Barij essence, Kashan, Iran), probiotic placebo daily and vitamin D placebo every 2 weeks, for 6 weeks orally.

Category

Treatment - Drugs

3

Description

Intervention group: Combined probiotic, including 2×10⁹ Lactobacillus acidophilus, 2×10⁹ Bifidobacterium bifidum, 2×10⁹ Lactobacillus reuteri, 2×10⁹ Lactobacillus fermentum daily, and vitamin D supplements (Zahravi, Tabriz, Iran), 50,000 IU vitamin D every 2 weeks, for 6 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar gynecology 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

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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

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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Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

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Name of organization / entity

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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