Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Clinical trial of the effect of synbiotic supplementation compared with the placebo on pregnancy outcomes in women with gestational diabetes

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of synbiotic supplementation on biomarkers of inflammation, oxidative stress and pregnancy outcomes in patients with gestational diabetes.

Design

Study design: Parallel double-blind (both patients and researchers) clinical trial.

Settings and conduct

Population and sample size: 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/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18-40 years with gestational diabetes mellitus (GDM) at 24-28 weeks' gestation will be included in this study. Exclusion criteria: Pre-eclampsia, eclampsia, hypo and hyperthyroidism, kidney or liver diseases, taking any probiotic and/or synbiotic products, smoker, insulin therapy after GDM diagnosis.

Intervention groups

Control group: Placebo oral capsule (Tak Gen Zist, Tehran, Iran), daily, for 6 weeks. Intervention group: Synbiotic oral capsule containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g) (Tak Gen Zist, Tehran, Iran), 0.8 g inulin, daily, for 6 weeks.

Main outcome variables

Outcomes: High-sensitivity C-reactive protein and nitric oxide (primary outcomes). Biomarkeres of oxidative stress and pregnancy outcomes (secondary outcomes).

General information

Reason for update

Due to an error, the request for an update in our website has been conducted after paper published. However, the revisions were in accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201704205623N108**
Registration date: **2017-04-27, 1396/02/07**
Registration timing: **retrospective**

Last update: **2019-11-30, 1398/09/09**
Update count: **1**

Registration date

2017-04-27, 1396/02/07

Registrant information

Name
Zatollah Asemi
Name of organization / entity
Kashan University of Medical Sciences
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Iran (Islamic Republic of)
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+98 36 1534 3570
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asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2016-05-19, 1395/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of synbiotic supplementation compared with the placebo on pregnancy outcomes in women with gestational diabetes

Public title
Effect of supplementation therapy in treatment of women with gestational diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women aged 18-40 years with gestational diabetes mellitus at 24-28 weeks' gestation

Exclusion criteria:
Pre-eclampsia Eclampsia Hypo and hyperthyroidism Kidney or liver diseases Taking any probiotic and/or synbiotic products Smoker Insulin therapy after GDM diagnosis

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 according to balanced blocked randomisation will be randomly allocated into two treatment groups to take either supplement or placebo. Randomization will be done by the use of Stat Trek 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 Clinic who is not involved in the trial and not aware of random sequences will allocate the numbered bottles of capsules to participants. Supplements and placebo are in the same packaging at the pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of drug and after analyzing the data, packet codes are decoded.

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
Markazi

Postal code
3814113634

Approval date
2016-04-18, 1395/01/30

Ethics committee reference number
IR.IUMS.REC.1395.9311290004

Health conditions studied

1

Description of health condition studied
Gestational diabetes

ICD-10 code
E28.2

ICD-10 code description
Diabetes mellitus in pregnancy, unspecified

Primary outcomes

1

Description
High sensitivity C-reactive protein

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

Method of measurement
ELISA kit

2

Description
Nitric oxide

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

Method of measurement
Spectrophotometry

Secondary outcomes

1

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

2

Description
Newborns' weight
Timepoint
The first 24 h after birth
Method of measurement
Scale

3

Description
Polyhydramnios
Timepoint
After the intervention
Method of measurement
Sonography

4

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

5

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

6

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

7

Description
Newborn's head circumference
Timepoint
Delivery time
Method of measurement
Girth measuring tape

8

Description
Newborn's bilirubin
Timepoint
Delivery time
Method of measurement
Enzymatic kit

9

Description
Apgar score
Timepoint
Delivery time
Method of measurement
Clinical observation

10

Description
Preterm delivery
Timepoint
After delivery
Method of measurement
Medical record

11

Description
Maternal pre-eclampsia
Timepoint
After delivery
Method of measurement
Medical record

12

Description
Newborns' hospitalization
Timepoint
After delivery
Method of measurement
Medical record

13

Description
Maternal hospitalization
Timepoint
After delivery
Method of measurement
Medical record

14

Description
Newborns' hypoglycemia
Timepoint
After delivery
Method of measurement
Enzymatic kit

Intervention groups

1

Description
Control group: Placebo oral capsule (Tak Gen Zist, Tehran, Iran), daily, for 6 weeks.
Category
Treatment - Drugs

2

Description
Intervention group: Synbiotic oral capsule containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g) (Tak Gen Zist, Tehran, Iran), 0.8 g inulin, daily, for 6 weeks.
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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1168743514
Phone
+98 21 8805 2248
Email
karamali.maryam2@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
Street address
Vice chancellor for research, Iran University of Medical Sciences, Hemmat Highway, Tehran
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Postal code
1449614535
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research@iums.ac.ir
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

Person responsible for general inquiries

Contact
Name of organization / entity
Kashan University of Medical Sciences
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Position
PhD of 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