Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

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

Protocol summary

Study aim
The aim of this study is to determine the effects of probiotic supplementation on biomarkers of inflammation and oxidative stress in patients with 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
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: Patients with gestational diabetes aged 18 to 40 years. Exclusion criteria: Placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism, urinary tract infection, smokers, kidney or liver diseases and insulin therapy during intervention

Intervention groups
Intervention: Patients will be assigned into two groups to receive probiotic (n=30) or placebo (n=30) per day. Probiotic and placebos capsules are similar in shape and size.

Main outcome variables
Outcomes: Inflammatory markers (primary outcomes), and biomarkers of oxidative stress and pregnancy outcomes (secondry outcomes) signaling pathway will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201611115623N91**
Registration date: **2016-11-23, 1395/09/03**
Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**
Update count: **1**

Registration date
2016-11-23, 1395/09/03

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 36 1534 3570

Email address
asemi_z@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date
2016-04-07, 1395/01/19

Expected recruitment end date
2016-05-08, 1395/02/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of probiotic supplementation compared with the placebo on pregnancy outcomes 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:
Placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Urinary tract infection Smokers Kidney or liver diseases Insulin therapy during 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: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the use of computer-generated random numbers.
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 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
1449614535
Approval date
2016-04-06, 1395/01/18
Ethics committee reference number
IR.IUMS.REC 1394.9111290001

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

2

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

3

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

4

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

5

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

6

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

7

Description
Polyhydramnios
Timepoint
Post-intervention
Method of measurement
Sonography

8

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

9

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

10

Description
Apgar score
Timepoint
Delivery time
Method of measurement
Clinical observation

11

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

12

Description
Preterm delivery
Timepoint
After delivery
Method of measurement
Medical record

13

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

14

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

Intervention groups

1

Description
Intervention group: Probiotic capsule containing four 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), daily, for 6 weeks orally.
Category
Treatment - Drugs

2

Description
Control group: Placebo (Tak Gen Zist, Tehran, Iran), 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
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
akbarabadihosp@yahoo.com

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
Province
Tehran
Postal code
009886704768
Phone
+98 21 8670 4768
Email
PR@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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
Phone
+98 31 5546 3378
Email
asemi_z@kaums.ac.ir

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
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 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