

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 (secondary 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)

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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* (2×10^9 CFU/g), *Lactobacillus casei* (2×10^9 CFU/g) and *Bifidobacterium bifidum* (2×10^9 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 centers1**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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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Seyed Ali Javad Moosavi

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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, 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

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Full name of responsible person

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Contact

Name of organization / entity

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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