

# 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 (2×10<sup>9</sup> CFU/g), Lactobacillus casei (2×10<sup>9</sup> CFU/g) and Bifidobacterium bifidum (2×10<sup>9</sup> 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). Biomarkers 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

##### 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

2016-04-19, 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 (2×10<sup>9</sup> CFU/g), Lactobacillus casei (2×10<sup>9</sup> CFU/g) and Bifidobacterium bifidum (2×10<sup>9</sup> 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

##### City

Tehran

##### Province

Tehran

##### Postal code

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 86701

##### Email

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

##### 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

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##### Province

Isfahan

##### Postal code

81151-87159

##### Phone

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##### Fax

##### Email

asemi\_r@yahoo.com

##### 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

Ph.D.

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**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

**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