

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Clinical trial of the effect of Synbiotic supplementation compared with the placebo on metabolic profiles in patients with gestational diabetes

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of synbiotic supplementation on metabolic profiles in patients with gestational diabetes.

##### Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive synbiotic supplements (n=35) or placebo (n=35).

##### Settings and conduct

Among patients with gestational diabetes referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 70 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 synbiotic or probiotic including probiotic yogurt, kefir and other fermented foods, taking insulin, placenta abruption, pre-eclampsia, eclampsia, hypo and hyperthyroidism, smokers, kidney or liver diseases.

##### Intervention groups

Intervention group: Synbiotic capsule daily (Tak Gen Zist, Tehran, Iran) for 6 weeks orally. Control group: Placebo capsule (Tak Gen Zist, Tehran, Iran), for 6 weeks orally.

##### Main outcome variables

Outcomes: Insulin Metabolism (primary outcomes) and lipid profiles (secondary outcomes) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201605085623N77**

Registration date: **2016-05-11, 1395/02/22**

Registration timing: **retrospective**

Last update: **2019-09-19, 1398/06/28**

Update count: **1**

##### Registration date

2016-05-11, 1395/02/22

##### 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

Arak University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2016-03-19, 1394/12/29

##### 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 metabolic profiles in patients with gestational diabetes

##### Public title

Effect of supplementation in treatment of patients with gestational diabetes

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Patients with gestational diabetes Aged 18 to 40 years

#### **Exclusion criteria:**

Taking synbiotic or probiotic including probiotic yogurt, kefir and other fermented foods Taking insulin Placenta abruption Pre-eclampsia Eclampsia Hypo and hyperthyroidism Smokers Kidney or liver diseases

### **Age**

From **18 years** old to **40 years** old

### **Gender**

Female

### **Phase**

2

### **Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

### **Sample size**

Target sample size: **70**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and  $\geq$ 25 kg/m<sup>2</sup>) and age (<30 and  $\geq$ 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**

Single

### **Other design features**

Random assignment will be done by the use of computer-generated random numbers.

## **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**

Arak

### **Province**

Markazi

### **Postal code**

1771844351

### **Approval date**

2016-02-19, 1394/11/30

### **Ethics committee reference number**

IR.ARAKMU.REC.1395.22

## **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**

Questionnaire

## **Secondary outcomes**

### 1

#### **Description**

Triglycerides

#### **Timepoint**

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

#### **Method of measurement**

Enzymatic kit

### 2

#### **Description**

Cholesterol

**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**

LDL-cholesterol

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**5**

**Description**

VLDL-cholesterol

**Timepoint**

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

**Method of measurement**

Enzymatic kit

**Intervention groups**

**1**

**Description**

Intervention group: Probiotic supplements 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), 800 mg inulin, daily, for 6 weeks orally.

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Placebo, daily, for 6 weeks orally.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Kosar Clinic

**Full name of responsible person**

Mehri Jamilian

**Street address**

Emam Khomeyni Avenue, Arak

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**Phone**

+98 31 5546 3378

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jamilian.mehri@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Mohammad Rafiee

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

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Mohammad-Rafiee@Aums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

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**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable