Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥25 kg/m2) and age (<30 and ≥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 (2×109 CFU/g), Lactobacillus casei (2×109 CFU/g) and Bifidobacterium bifidum (2×109 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
City
Arak
Province
Markazi
Postal code
1771844351
Phone
+98 31 5546 3378
Email
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
Street address
Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak
City
Arak
Province
Markazi
Postal code
1771844351
Phone
+98 31 5546 3378
Email
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
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
1771844351
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

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_r@yahoo.com
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_r@yahoo.com
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