

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Effect of symbiotic supplementation on lipid profile, glycemic control and hs-CRP in women with gestational diabetes mellitus

Protocol summary

Summary

(1)Objectives: The effect of Symbiotic supplements on some biochemical characteristics in women with gestational diabetes mellitus. (2)Design: Randomized Double blind clinical Trial. (3)Setting and conduct: The process of Balanced Block selection were performed until all the 90 patients were random divided into 2 groups. The first blood samples were taken from the subjects after assessing their anthropometric measurements and taking their 24 hour food recalls. Then, they were asked to consume either of the symbiotic or placebo capsules for 6 weeks. Subjects were asked not to consume any symbiotic-containing food, yogurt or its products during the intervention. More so, they were asked not to change their regular diet, activity and medicine during the study. Second Blood samples were also taken after an overnight fasting and before-after analysis was performed finally. (4)Participants including major eligibility criteria: (4-a) Major Inclusion Criteria: Women with gestational diabetes mellitus. (4-b) Major Exclusion Criteria: A history of diabetes before pregnancy; blood pressure; tobacco and alcohol use; Having Eclampsia and pre-eclampsia; clinical signs of some chronic or acute diseases. (5)Intervention: Group 1 (Intervention group) who daily received 1 capsule containing 500 mg probiotic supplements after the lunch meal, and Group 2 (Placebo group) who received placebo as the same, all for 6 weeks. (6)Main outcome measures (Variables): Fasting blood sugar, Serum insulin, Total Cholesterol, LDL-C, HDL-C, TG and HOMA-IR, Insulin sensitivity

General information

Acronym

Symbiotic and Gestational Diabetes Mellitus

IRCT registration information

IRCT registration number: **IRCT201511183140N16**

Registration date: **2015-12-29, 1394/10/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-29, 1394/10/08

Registrant information

Name

Bahram Pourghassem Gargari

Name of organization / entity

Health and Nutrition Faculty, Tabriz University of medical sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-11-09, 1394/08/18

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of symbiotic supplementation on lipid profile, glycemic control and hs-CRP in women with gestational diabetes mellitus

Public title

Effect of symbiotic supplementation on lipid profile, glycemic control and hs-CRP

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion/exclusion criteria : Inclusion criteria: All pregnant women diagnosed with gestational diabetes (women who began treatment with insulin.); The age range was 18 to 40 ; 28-24 weeks of pregnancy ; Singleton pregnancies; Lack of pre-eclampsia and eclampsia. Exclusion criteria: Pregnant women with a history of diabetes before pregnancy; Gestational hypertension (blood pressure equal to or greater than 140/90, without proteinuria is created at mid-pregnancy.); Age <18 years and over 40 years; Women with a history Multiple pregnancy or fetal malformations; Women in pregnancy week> 28 ; People who show sensitivity to symbiotic or placebo capsules during the study; Those consume with less than 90% symbiotic or placebo capsules ; Tobacco and alcohol use; Pregnant women with a history of diseases affecting the metabolism of glucose, infection, chronic diseases, women consumers of antibiotics; Pregnant women with diseases such as immune deficiency, heart valve disease, syndrome Short bowel ischemia risk; If someone without pre-eclampsia and eclampsia recruited, but the poisoning was diagnosed during the study will be excluded

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice Chancellor for Research and Technology

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Third floor, Central building No. 2, Tabriz University of Medical Sciences, Golgasht- street

City

Tabriz

Postal code**Approval date**

2015-11-09, 1394/08/18

Ethics committee reference number

TBZMED.REC.1394.688

Health conditions studied**1****Description of health condition studied**

gestational diabetes mellitus

ICD-10 code

O24.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes**1****Description**

HOMA-IR

Timepoint

Baseline and after 6 weeks

Method of measurement

Formula

2**Description**

Insulin Sensitivity

Timepoint

Baseline and after 6 weeks

Method of measurement

QUICKI Index

3**Description**

Fasting Blood Sugar

Timepoint

Baseline and after 6 weeks

Method of measurement

Biochemical Analysis

4**Description**

Serum Insulin

Timepoint

Baseline and after 6 weeks

Method of measurement

ELIZA

5**Description**

Lipid profile: Total cholesterol, Triglyceride, HDL-C, LDL-C

Timepoint

Baseline and after 6 weeks
Method of measurement
Biochemical Analysis

6

Description
hs-CRP
Timepoint
Baseline and after 6 weeks
Method of measurement
ELIZA

Secondary outcomes

1

Description
Dietary Factors
Timepoint
Baseline and after 6 weeks
Method of measurement
3 day 24 hour food recall questionnaire

Intervention groups

1

Description
Intervention Group: Women with Gestational Diabetes Mellitus receive 1 Lactofem Symbiotic Capsule one a day (After lunch), for 6 weeks. Each capsule contains 500 mg Symbiotic which precisely consist of the following strains and species 1) Lactobacillus acidophilus 5×10^{10} CFU/g 2) Lactobacillus plantarum 1.5×10^{10} CFU/g 3) Lactobacillus fermentum 7×10^9 CFU/g 4) Lactobacillus Gasseri 2×10^{10} CFU/g
Category
Treatment - Drugs

2

Description
Placebo Group: Receiving 1 Placebo Capsules ones a day (after lunch), containing lactose, Colloidal silicon dioxide, Mg stearate, talc, Magnesium Stearate for 6 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Zohoor Nabhani
Street address
Tehran, Keshavarz Blvd, Imam Khomeini Hospital
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Nutrition Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. AliReza Ostad Rahimi
Street address
Faculty of Nutrition, Attar street, Golgasht street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutrition Research Center, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty