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

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Name of organization / entity

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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
Street address
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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Full name of responsible person

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Position

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Person responsible for scientific

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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