Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Probiotics in comparison with placebo on glucose metabolism, weight changes and inflammatory and oxidative stress indices in women with gestational diabetes mellitus

Protocol summary

Summary

The aim of the current double-blind, placebo controlled randomized clinical trial is to study the effects of Probiotic supplement containing Lactobacillus acidophilus, LA-5 and Bifidobacterium, BB12 on weight changes, glucose metabolism and inflammatory and oxidative stress indices in women with gestational diabetes mellitus. Sixty four volunteer pregnant women, singleton primigravida, with gestational diabetes mellitus diagnosis without the history of diabetes, hypoglycemic drug usage, chronic disease, smoking, alcohol consumption and Probiotic food products consumption in current two weeks will be included in the study and in case of need for insulin or other hypoglycemic drugs, they will be excluded. All the participants will be divided into experimental and control groups using random sampling method and they will receive one Probiotic or placebo capsule along with dietary advice for eight consecutive weeks, respectively. Ten milliliter blood drawn via venous puncture will be subjected for analysis of biochemical markers including glucose metabolism indices (serum glucose and insulin, HOMA-IR and QUICKI indices), inflammatory indices (highly sensitive C-reactive protein/hs-CRP, TNF-α and Interleukin-6) and oxidative stress indices (total antioxidant capacity/TAC, malondialdehyde/MDA, superoxide dismutase/SOD, glutathione reductase/GSH-R, glutathione peroxidase/GSH-Px and uric acid). Also weight changes will be determined by digital scale before and after intervention. The data will be entered in related software and analyzed by appropriate statistical methods to study the effect of the intervention on serum levels of the selected bio-markers and weight changes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405181597N3**
Registration date: **2014-06-16, 1393/03/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-16, 1393/03/26

Registrant information

Name

Majid Hajifaraji

Name of organization / entity

National Nutrition & Food Technology Research Institute of IRAN (NNFTRI)

Country

Iran (Islamic Republic of)

Phone

+98 21 2236 0661

Email address

m39faraji@yahoo.com

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-05-29, 1393/03/08

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Probiotics in comparison with placebo on glucose metabolism, weight changes and inflammatory and oxidative stress indices in women with gestational diabetes mellitus

Public title
Effect of Probiotics on diabetes mellitus arising in pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: nulliparity; diagnosis of gestational diabetes mellitus between 24 weeks and 0 days and 28 weeks and 6 days of pregnancy with oral screening test; fasting blood glucose level between 92- 126 mg/dl; body mass index 18.5 and more; nulliparity; negative history of f diabetes mellitus before the current pregnancy; chronic diseases; Smoking and/or alcohol consumption; probiotic food products consumption through current 2 weeks; antibiotic usage through current month; acute GI condition through current month and glucocorticoid and immunosuppressor drugs usage Exclusion criteria: need for insulin or other hypoglycemic drugs; corticosteroids or immune-suppressants usage or acute GI condition during the study
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Patients will be randomly included in intervention and control groups through sequential matching based on pre-pregnancy body mass index (18.5 to 24.9, 25 to 29.9 and 30 and more kilograms per square meter) and fasting plasma glucose (92 to 104 and 105 and more milligrams per deciliter)

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The International Branch of Shahid Beheshti University of Medical Sciences and Health Services
Street address
19, Shahid Abbasspour St., Vali-Asr Ave., Tehran, Iran
City
Tehran
Postal code
Approval date
2014-05-18, 1393/02/28
Ethics committee reference number
116.449

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
Fasting Blood Glucose
Timepoint
Before and after intervention
Method of measurement
Enzymatic

2

Description
Fasting Plasma Insulin
Timepoint
Before and after intervention
Method of measurement
Elisa

3

Description
Homeostatic Model Assessment/HOMA-IR
Timepoint
Before and after intervention
Method of measurement
Calculation

4

Description
Quantitative Insulin Sensitivity Check/QUICKI-index
Timepoint
Before and after intervention
Method of measurement

Calculation

Secondary outcomes

1

Description
Highly Sensitive-C Reactive Protein/hs-CRP
Timepoint
Before and after intervention
Method of measurement
Elisa

2

Description
Tumor Necrozing Factor Alpha/TNF-α
Timepoint
Before and after intervention
Method of measurement
Elisa

3

Description
Interleukine-6
Timepoint
Before and after intervention
Method of measurement
Elisa

4

Description
Toatal Antioxidant Capacity/TAC
Timepoint
Before and after intervention
Method of measurement
Elisa

5

Description
Malondialdehyde/MDA
Timepoint
Before and after intervention
Method of measurement
Enzymatic

6

Description
Glutathione Reductase/GSH-Red
Timepoint
Before and after intervention
Method of measurement
Elisa

7

Description
Superoxide Dismutase/SOD
Timepoint
Before and after intervention
Method of measurement
Elisa

8

Description
Glutathione Peroxidase/GSH-Px
Timepoint
Before and after intervention
Method of measurement
Enzymatic

9

Description
Uric Acid
Timepoint
Before and after intervention
Method of measurement
Enzymatic

10

Description
Weight
Timepoint
Before, 2 weeks, 4 weeks, 6 weeks and 8 weeks after intervention
Method of measurement
Digital scale

Intervention groups

1

Description
Control: in control group, 32 pregnant women after the entry qualifications, will take one tablet of placebo with the shape and color exactly similar to 4biocap for 8 weeks and variables will be analyzed before and after the intervention.
Category
Treatment - Drugs

2

Description
Intervention: in intervention group, 32 pregnant women after the entry qualifications will take one capsule of 4biocap containing 180 mg(>1 billion CFU) of a standardized, cream colored powder consisting of freeze-dried cultures of: Lactobacillus Acidophilus LA-5, Bifidobacterium, BB-12, Streptococcus Thermophilus, STY-31 and Lactobacillus Delbrueckii ssp. Bulgaricus, LBY-27, once a day for 8 weeks and variables will be analysed before and after the intervention.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital-Tabriz University of Medical Sciences

Full name of responsible person
Dr.Fateme Abbasalizadeh

Street address
Alzahra Hospital, Artesh St., Tabriz, Iran

City
Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences and Health Services

Full name of responsible person
Dr.Hamid Soori

Street address
International Branch, 19, Shahid Abbspour St., Vali-Asr Ave., Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Shahid Beheshti University of Medical Sciences and Health Services

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
Shahid Beheshti University of Medical Sciences and Health Services

Full name of responsible person
Neda Dolatkhah

Position
MD., Ph.D student of Nutrition Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
PhD(Clinical Nutrition), FNS MSc & PG Dipl., Research Associate Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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