

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 Abbaspour 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 \square containing 180 mg(>1 billion CFU) of a standardized, cream colored powder consisting of freeze-dried cultures of: Lactobacillus Acidophilus LA-5 \square , Bifidobacterium, BB-12 \square , 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 Abbaspour 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 Dolatkah

Position

MD., Ph.D student of Nutrition Sciences

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

PhD(Clinical Nutrition), FNS MSc & PG Dipl., Research Associate Professor

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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