

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of probiotic supplementation on inflammatory factors and biomarkers of oxidative stress in

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

The aim of this study is to determine the effects of probiotic supplementation on inflammatory factors and biomarkers of oxidative stress in pregnant women.

Last update: **2019-10-04, 1398/07/12**

Update count: **1**

Registration date

2015-03-10, 1393/12/19

Design

Study design: Double-blind randomized controlled clinical trial.

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Settings and conduct

Population and sample size: 60 pregnant women of eligible and referred to gynecology clinic affiliated to Arak University of Medical Sciences, Arak, Iran in the study will be selected.

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18-37 years will be included in this study. Exclusion criteria: Pregnant women with a recognized cause of recurrent miscarriages or a structural uterine abnormality, history of rheumatoid arthritis, thyroid and parathyroid, adrenal diseases, hepatic or renal failure.

Expected recruitment start date

2015-03-02, 1393/12/11

Expected recruitment end date

2015-03-31, 1394/01/11

Intervention groups

Intervention: Patients will be assigned to receive either probiotic supplement containing three strains of Lactobacillus acidophilus (2×10^9 CFU/g), Lactobacillus casei (2×10^9 CFU/g) and Bifidobacterium bifidum (2×10^9 CFU/g) (intervention group: n=30) or placebo (control group: n=30).

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Main outcome variables

Outcomes: Insulin and insulin resistance (primary outcomes) and biomarkers of oxidative stress, lipid and inflammation (secondary outcomes) will be quantified at study baseline and end-of-trial.

Scientific title

Effects of probiotic supplementation on inflammatory factors and biomarkers of oxidative stress in

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201503035623N38**

Registration date: **2015-03-10, 1393/12/19**

Public title

Effect of probiotic in the treatment of pregnant women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women aged 18-37 years

Exclusion criteria:

Pregnant women with a recognized cause of recurrent miscarriages or a structural uterine abnormality History of rheumatoid arthritis, thyroid and parathyroid Adrenal diseases Hepatic or renal failure.

Age

From **18 years** old to **37 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take probiotic supplements (n=30) or the standard diet (n=30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Arak University of Medical Sciences

Street address

Vice-chancellor for Education and Research, Sardasht Avenue, Arak

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Arak

Province

Markazi

Postal code

3848176941

Approval date

2014-09-08, 1393/06/17

Ethics committee reference number

19-167-93

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

Pregnancy

ICD-10 code

Z34.-

ICD-10 code description

Normal pregnancy

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

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

2**Description**

Insulin resistance

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

Secondary outcomes**1****Description**

Fasting blood sugar

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

2**Description**

Triglycerides

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

3**Description**

HDL-cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

4**Description**

Total cholesterol

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

5**Description**

VLDL

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

6**Description**

LDL

Timepoint

Baseline and End-of-trial

Method of measurement

Enzymatic kit

7**Description**

Total Antioxidant Capacity

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

8**Description**

Glutathione

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

9**Description**

Hs-CRP

Timepoint

Baseline and End-of-trial

Method of measurement

Elisa kit

10**Description**

Malondialdehyde

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

11**Description**

Nitric oxide

Timepoint

Baseline and End-of-trial

Method of measurement

Spectrophotometry

Intervention groups**1****Description**

Intervention group: Probiotic capsule containing three strains of *Lactobacillus acidophilus* (2×10⁹ CFU/g), *Lactobacillus casei* (2×10⁹ CFU/g) and *Bifidobacterium bifidum* (2×10⁹ CFU/g), daily, for 12 weeks orally.

Category

Treatment - Drugs

2**Description**

Control group: Placebo capsule, daily, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gynecology Clinic

Full name of responsible person

Mehri Jamilian

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Emam Khomeyni Avenue, Arak

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

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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

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Position

PhD of Nutrition

Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available