Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

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

Protocol summary

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.

Design
Study design: Double-blind randomized controlled clinical trial.

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.

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.

Intervention groups
Intervention: Patients will be assigned to receive either probiotic supplement containing three strains of Lactobacillus acidophilus (2×109 CFU/g), Lactobacillus casei(2×109 CFU/g) and Bifidobacterium bifidum (2×109 CFU/g) (intervention group: n=30) or placebo (control group: n=30).

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.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT201503035623N38**
Registration date: **2015-03-10, 1393/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-04, 1398/07/12**
Update count: **1**

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

Registrant information

Name
Zatollah Asemi

Name of organization / entity
Kashan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Arak University of Medical Sciences

Expected recruitment start date
2015-03-02, 1393/12/11

Expected recruitment end date
2015-03-31, 1394/01/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

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

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
City
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
Street address
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
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Person responsible for updating data

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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