Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Growing response to probiotic supplementation in pregnant women with intrauterine growth restriction

Protocol summary

Study aim
Growing response to probiotic supplementation in pregnant women at risk of intrauterine growth restriction

Design
Placebo-controlled clinical trial; with parallel groups; double-blinded; A randomized; design for 50 patients

Settings and conduct
Patient will be assigned into 2 groups with block randomization method. 25 patients will be treated by probiotic & aspirin and 25 patients will be received placebo & aspirin. Both groups will also request to fill in a questionnaire before start and after of treatment. Drugs are named to A and B and have been administered in the similar bottle. Before start of the study blood sample will be taken to relevant factors after that in double blind study one group will be received probiotic & asprine and the other two placebo & aspirin since diagnosis of high uterine artery resistance till 28 weeks At the end of the study blood sample is taken.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: 18 to 40 years old; Gravid one; Mean UAPI in the study > 2.35; gestational age of 11 to 13 weeks and six days . No history of specific disease
Exclusion criteria: Liver and kidney disease; Thyroid disorders; complete bed rest; BMI> 30

Intervention groups
50 subjects with high uterine arteries resistance will be assigned into 2 groups with block randomization method,25 patients will be treated by Probilitic and Aspirin and 25 patients will be received be palcebo & Aspirine

Main outcome variables
Estimate fetal weight, TAC, GPX, MDA, lipid profile (Total cholesterol, triglyceride), FBS, Insulin resistance, hs-CRP , NO

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140525017827N13**
Registration date: **2021-11-20, 1400/08/29**
Registration timing: **prospective**

Last update: **2021-11-20, 1400/08/29**
Update count: **0**

Registration date
2021-11-20, 1400/08/29

Registrant information

Name
Nasrin Asadi

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Growing response to probiotic supplementation in pregnant women with intrauterine growth restriction

Public title
Probiotic supplementation in pregnant women with intrauterine growth restriction
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 40 years Women's BMI should be in the range 19.5-29.9 Gravid 1 Mean UAPI in the study group > 2.53 Gestational age 11 to 13 weeks and six days uterine vascular resistance is high
Exclusion criteria:
Liver and kidney disease Thyroid disorders Complete bed rest
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The treatment allocation list is already designed on Block Balanced Randomization Method by the computer software (https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html) .They are divided into two intervention or control groups by block sizes of 4 and 6 with an allocation ratio of 1:1. Any eligible patient will be given a 1 to 50 code after obtaining informed consent in order to visit the clinic and based on above block, they receive A or B drug. The drug distributor doesn’t have a role in the treatment plan and data analysis. The patients, researcher, data analyzer are not aware of the type of treatment for each patient. Finally, the patients will be followed by their own codes
Blinding (investigator's opinion)
Double blinded
Blinding description
Probiotic and placebo have been administered in the similar bottles, so patients and researchers were unable to detect which one was Probiotic or placebo. Our nurse colleague in this study in hospital delivered formulations to the participants of the study according to the randomized block table. She was unaware of the content of the bottles. The researcher had no information about formulation used by each patient while visiting them. At the end of the study, the formulations were decoded and the patients assigned to each group were identified
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences - Zand St - Shiraz
City
Shiraz
Province
Fars
Postal code
34786-71946
Approval date
2019-05-19, 1398/02/29
Ethics committee reference number
IR.SUMS.REC.1398.507

Health conditions studied

1

Description of health condition studied
Intrauterine growth restriction
ICD-10 code
o36.5
ICD-10 code description
Intrauterine growth restriction

Primary outcomes

1

Description
Total plasma antioxidant capacity (TAC)
Timepoint
before starting medications and at 28 weeks
Method of measurement
Benzie and Strain methods by calorimetric method using Cusabio Biotech Co

2

Description
Plasma Glutathione (GPX) Activity
Timepoint
Before starting medications and at 28 weeks
Method of measurement
Beutler method using Cusabio Biotech Co

3

Description
Malondialdehyde (MDA)
Timepoint
Before starting medications and at 28 weeks
Method of measurement
TBARS method

Secondary outcomes

1

Description
Lipid profiles of total cholesterol, HDL-C and triglyceride concentrations
Timepoint
Before starting medications and at 28 weeks
Method of measurement
Enzymatic method using Selectra II autoanalyzer

2

Description
Inflammatory markers A. Inflammatory factor hs-CRP
Timepoint
Before starting medications and at 28 weeks
Method of measurement
ELISA device (immunoassay method)

3

Description
Nitric Oxide Inflammatory Marker Nitric Oxide Amount
Timepoint
Before starting medications and at 28 weeks
Method of measurement
The grease reaction is measured

4

Description
Fasting blood sugar and insulin resistance
Timepoint
Before starting medications and at 28 weeks
Method of measurement
Glucose oxidase / peroxidase assay using commercially available kits

Intervention groups

1

Description
Intervention group: 25 of participant were treated with probiotic supplements of probiotic bacteria in the present study, including: Lactobacillus acidophilus 2CFU, Bifidobacterium bifidum , Lactophilus casei and Lactobacillus fermentum , which is prepared from Tehran Zig Tak Gene Company, twice a day. Diagnosis up to 28 weeks of pregnancy and aspirine 160 mg before sleep
Category
Treatment - Drugs

2

Description
Control group: 25 patient will be received placebo made by the Faculty of Pharmacy of Shiraz university of medical sciences, twice per day and aspirine 160 mg before sleep
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Perinataology clinic
Full name of responsible person
Sedighe Youosefi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz 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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Sedighe Youosefi

Position
Fellow ship perinataology

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Associate professor

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Subspecialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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

Title and more details about the data/document
Experimental results, ultrasound of patients in both groups, Statistical Results

When the data will become available and for how long
End of august 2022

To whom data/document is available
healthcare professional- ācademic members of universities

Under which criteria data/document could be used

An official request from the organization

From where data/document is obtainable

To researchers responsible for responding to this plan Address: Maternal- Fetal Medicine (Perinatology), Hafez Hospital, Chamran Ave., Shiraz, Iran Tel: +98-71-36128257,+98-36122285 Fax: 07136479830 postal code: 7193635899

What processes are involved for a request to access data/document

Request to Vice-Chancellor for Research and Technology Affairs, Written request Coordinated by the ethics committee 2 months

Comments