Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of oral probiotic lactofem on metabolic parameters in overweight pregnant women referred to prenatal clinics of the shiraz hospitals in 2016

Protocol summary

Study aim

Effect of oral probiotic lactofem on metabolic parameters in overweight pregnant women referred to prenatal clinics of the shiraz hospitals in 2016

Design

Effect of oral probiotic capsules Lactofem on metabolic parameters: this research is a double blinded placebo-controlled trial. fasting glucose, lipid profiles, diastolic and systolic blood pressure in pregnant women 18 to 35 years who were overweight and at weeks 16 and 20 of pregnancy on the basis of the questionnaire and randomly selected configuration block design is divided into two groups: placebo and intervention. Each group of 64 people divided into two lactofem capsules daily or placebo until the end of pregnancy. the intervention done at 20 weeks and at the end of 28 weeks and 36 weeks of pregnancy, systolic and diastolic blood pressure and fasting blood samples to assess the lipid profile and glucose, and samples blood sugar 2 hours after breakfast, evaluating.Data evaluation done with placebo and intervention groups then results will be compared with statistical methods.

Settings and conduct

This study is an interventional study of double-blind, controlled clinical trial that studied the effect of lactobacillus probiotic capsule on metabolic parameters of overweight Pregnant women.This research is done in selected hospitals in Shiraz.

Participants/Inclusion and exclusion criteria

Pregnant women aged 18 to 35 years and the gestational age of 20 to 24 weeks, with a BMI of over 25, If they have criteria for entering the study, they will be selected.

Intervention groups

An interventional study is a double-blind clinical controlled trial in which to study the effect of lactofem probiotic capsule on Metabolic Indicators of Overweight Pregnant Women in two groups, oral probiotic capsule (test) and placebo (control) are checked.

Main outcome variables

Comparison of fasting blood sugar level before intervention at 20 weeks, and after the intervention at weeks 28 and 36 pregnancy in in test and control groups. Comparison of 2hpp level before intervention at 20 weeks, and after the intervention at weeks 28 and 36 pregnancy in in test and control groups. Comparison of mean lipid profile before intervention at 20 weeks, and after the intervention at weeks 28 and 36 pregnancy in in test and control groups. Comparison of systolic and diastolic blood pressure, before intervention at 20 weeks, and after the intervention at weeks 28 and 36 pregnancy in in test and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161025030502N2**
Registration date: **2018-02-04, 1396/11/15**
Registration timing: **retrospective**

Last update: **2018-02-04, 1396/11/15**
Update count: **0**

Registration date

2018-02-04, 1396/11/15

Registrant information

Name

Elnaz Gharib

Name of organization / entity

School of Nursing and Midwifery, Shiraz University

Country

Iran (Islamic Republic of)

Phone

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stud2452166723@sums.ac.ir

Recruitment status
Recruitment complete
Funding source
Shiraz university of medical science budget

Expected recruitment start date
2016-11-21, 1395/09/01
Expected recruitment end date
2017-01-20, 1395/11/01
Actual recruitment start date
2016-11-21, 1395/09/01
Actual recruitment end date
2017-01-20, 1395/11/01
Trial completion date
empty

Scientific title
Effect of oral probiotic lactofem on metabolic parameters in overweight pregnant women referred to prenatal clinics of the shiraz hospitals in 2016

Public title
Effect of oral probiotic lactofem on metabolic parameters in overweight pregnant women referred to prenatal clinics of the shiraz hospitals in 2016
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Tendency to participate in research pre-pregnancy body mass index between 25 > BMI> 30 (which is selected by questionnaire) 20 to 24 weeks gestational age The lack of any disease, including diabetes, high blood pressure, liver disease, kidney, adrenal and thyroid, Hypercholesterolemia and bleeding Do not use medications that affect glucose metabolism and fat and blood pressure normal diet (based on questionnaires is selected) non-smoking
Exclusion criteria:
No proper use of probiotics any allergies to medication or placebo The occurrence of acute bleeding pre-eclampsia
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **144**
Actual sample size reached: **144**
Randomization (investigator's opinion)
Randomized
Randomization description
A permutation block design will be used after selecting each sample, we assign it to the treatments B, A using the random numbers table. Let's put the number from 0 to 4 in AB's permutation, and 5 to 9 in the BA reversal.
Blinding (investigator's opinion)
Double blinded
Blinding description
Probiotics are given blindly. probiotic capsule and placebo are completely prepared by the pharmaceutical company. After encoding, they are randomly assigned to groups a and b. After completing sampling and collecting information, the group code is given to the researcher. At the beginning of the study, the patient is described as being in the A or B group Which may include oral probiotic capsules or placebo.
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 - Zand Street - Next to the Red Crescent - Sakhtmtn Central University - Class 7 - Research Shiraz
City
Shiraz
Province
Fars
Postal code
1978 -71345
Approval date
2016-10-10, 1395/07/19
Ethics committee reference number
IR.SUMS.REC.1395.126

Health conditions studied

1

Description of health condition studied
Certain conditions originating in the perinatal period
ICD-10 code
P96.8
ICD-10 code description
Other specified conditions originating in the perinatal period

Primary outcomes

1

Description

Fasting blood sugar-Fasting glucose and blood sugar 2 hours after breakfast

Timepoint

20 week before intervention,28 and 36 week, after intervention

Method of measurement

Blood sample

2

Description

systolic and diastolic blood pressure

Timepoint

20 week before intervention,28 and 36 week, after intervention

Method of measurement

Blood sample

3

Description

plasma lipids

Timepoint

20 week before intervention,28 and 36 week, after intervention

Method of measurement

Blood sample

Secondary outcomes

1

Description

Reduce the blood sugar

Timepoint

20 week before intervention,28 -36 week after intervention

Method of measurement

نمونه خون

2

Description

Reduce the blood pressure

Timepoint

20 week before intervention,28 -36 week after intervention

Method of measurement

mercury manometer

3

Description

Reduce the serum lipids

Timepoint

20 week before intervention,28 -36 week after intervention

Method of measurement

نمونه خون

Intervention groups

1

Description

In the intervention group one probiotic capsule every 12 hours be administered Of the week 20 to 36 of pregnancy.

Category

Prevention

2

Description

Case-control study. In the control group one placebo capsule every 12 hours be administered Of the week 20 to 36 of pregnancy.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Hafez hospital

Full name of responsible person

Dr. Fateme Poordast

Street address

School of medicine, Emam hossein square, Zand street, Shiraz

City

Shiraz

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Postal code

7134845794

Phone

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Email

ta.poordast@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vice President of Research Shiraz University of Medical Siences-Dr.Hashemi Basir

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7th floor,Central building of Shira Universityof Medical Siences,Next to the Red Crescen ,Zand Street

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Email
vcrdep@sums.ac.ir
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
School of Nursing and Midwifery, Shiraz University of Medical Siences
Full name of responsible person
Sara Azima
Position
Masters of Midwifery
Latest degree
Master
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Person responsible for updating data

Contact
Name of organization / entity
The School of Nursing and Midwifery of Shiraz
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Elnaz Gharib
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Latest degree
Bachelor
Other areas of specialty/work
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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