

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of probiotic capsules and placebo on fasting blood sugar and metabolic parameters in pregnant woman with gestational diabetes or impaired glucose tolerance test

Protocol summary

Summary

Study is a randomized controlled double-blind trial that comparison effects of use of probiotic supplements, or placebo on the level of fasting blood glucose, lipids and blood pressure in women with impaired glucose tolerance or gestational diabetes. One hundred Patients that age of pregnancy below 34 weeks without medication refer to prenatal clinic in Al-Zahra hospital of Guilan University of Medical Sciences in 1394. Diagnosis based on a three-hour oral glucose tolerance test based on carpenter criteria by internist. Inclusion criteria were single pregnancy; gestational diabetes or impaired glucose tolerance in recent pregnancy; less than 34 weeks gestational age and don't use of medication such as insulin or metformin. Exclusion criteria included overt diabetes; fetal anomalies; with out prenatal care and do not use of probiotics. The first step during the first visit after 12 hours of fasting, blood sample to measure the FBS, triglyceride, total cholesterol, HDL and LDL is taken. The patient's blood pressure in standard conditions after 10 minutes of rest are recorded. Bottles contains 30 capsules (type A and B) were given randomly for a month. After 4 weeks, second blood sample were taken to measure the FBS, triglyceride and total cholesterol, HDL and LDL. The patient's blood pressure is recorded under standard condition.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110310089N4**

Registration date: **2016-02-01, 1394/11/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-01, 1394/11/12

Registrant information

Name

Roya Faraji Darkhaneh

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1322 5624

Email address

h_fertility@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of probiotic capsules and placebo on fasting blood sugar and metabolic parameters in pregnant woman with gestational diabetes or impaired glucose tolerance test

Public title

Impact of probiotics in gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusions criteria: single pregnancy; new diagnosis of IGT or GDM in the current pregnancy; <34 weeks' gestation; without insulin or metformin therapy.
 Exclusions criteria: pregestational diabetes; fetal anomaly; without follow; do not use of probiotics

Age
 From **18 years** old to **49 years** old

Gender
 Female

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **100**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Guilan University of Medical Sciences

Street address
 Reaserch and technology adjustancy of Guilan university of Medical sciences, Gas palace, Rasht, Guilan,Iran

City
 Rasht

Postal code
 41938-93345

Approval date
 2014-10-19, 1393/07/27

Ethics committee reference number
 IR.GUMS.REC.1394.308

Health conditions studied

1

Description of health condition studied
 Gestational diabetes

ICD-10 code
 024.4

ICD-10 code description

Diabetes mellitus arising in pregnancy

Primary outcomes

1

Description
 Probiotics user

Timepoint
 Baseline

Method of measurement
 use probiotic capsule

2

Description
 placebo user

Timepoint
 baseline

Method of measurement
 use placebo capsule

Secondary outcomes

1

Description
 Fasing blood glucose

Timepoint
 Baseline and 4 weeks after intervention

Method of measurement
 Blood sample

2

Description
 Triglyceride

Timepoint
 Baseline and 4 weeks after intervention

Method of measurement
 Blood sample

3

Description
 Total cholesterol

Timepoint
 Baseline and 4 weeks after intervention

Method of measurement
 Blood sample

4

Description
 Low density lipoprotein(LDL)

Timepoint
 Baseline and 4 weeks after intervention

Method of measurement
 Blood sample

5

Description

High density lipoprotein

Timepoint

Baseline and 4 weeks after intervention

Method of measurement

Blood sample

6

Description

Blood pressure

Timepoint

Baseline and 4 weeks after intervention

Method of measurement

With manometer in standard position

Intervention groups

1

Description

Give to patients a bottle contains 30 capsules of probiotics with brand Lactofem from Zist takhmir company that is for a month. Capsules should be taken daily.

Category

Treatment - Drugs

2

Description

Give to patients a bottle contains 30 capsules of placebo with from Zist takhmir company that is for a month. Capsules should be taken daily.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Arezoo Fani

Street address

Alzahra hospital, Namjoo street, Rasht, Guilan, Iran

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Abtin Heydarzadeh

Street address

Research and technology adjutancy of Guilan University of Medical Sciences, Gas palace, Rasht, Guilan, Iran

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan University of Medical Sciences

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

Alzahra hospital

Full name of responsible person

Arezoo Fani

Position

Resident of gynecology

Other areas of specialty/work

Street address

Alzahra hospital, Namjoo street, Rasht, Guilan, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Resident of gynecology

Other areas of specialty/work

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Alzahra hospital, Namjoo street, Rasht, Guilan, Iran

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Person responsible for updating data

Contact

Name of organization / entity
Alzahra hospital
Full name of responsible person
Arezoo Fani
Position
Resident of gynecology
Other areas of specialty/work
Street address
Alzahra hospital, Namjoo street, Rasht, Guilan, Iran
City
Rasht
Postal code

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