

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of probiotic capsule on prevention of gestational diabetes in high risk pre-diabetic pregnant women

Protocol summary

Study aim

Comparison of abnormal OGTT in probiotic capsule consumers and control group in high risk pre-diabetic women.

Design

A Phase 3 clinical trial, with a control group, three blind, randomized allocation, 243 eligible pregnant women. Cluster sampling convenience method on pregnant women with high risk pre-diabetics referred to Mashhad health centers.

Settings and conduct

Packaging and encodings of capsules will be done by the pharmacist. The study will be triple blind. Research units will be pregnant women referred to Mashhad health centers who are eligible to enter the study. The intervention will be performed within 70 days(12 week) and then at 26-28 weeks in all three groups, OGTT (oral glucose tolerance test) will be measured and evaluated.

Participants/Inclusion and exclusion criteria

Willingness to participate, Reading and writing literacy, no history of cow's milk allergy, having a contact number, being pre-diabetics, The gestational age between 14 and 16 weeks, lack of continuous antibiotic use in the last 3 months, absence of immune disorders or medical illness, Lack of pregnancy by in vitro fertilization, normal screening tests for fetal abnormalities in the first stage, Single pregnancy, no decision to terminate pregnancy, no smoking, no stressful incident in the last 3 months, no severe mental illness.

Intervention groups

Routine care includes exercise and Pre-diabetes diet in all three groups of probiotic, placebo and control. In the Probiotic Group 1 probiotic capsule daily and in the placebo group 1 placebo for 12 weeks from 14-16 until 26-28 weeks of gestation. In the control group, routine health care will receive, include education pre-diabetic diet and exercise.

Main outcome variables

Abnormal OGTT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180509039595N1**

Registration date: **2018-06-29, 1397/04/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-29, 1397/04/08**

Update count: **0**

Registration date

2018-06-29, 1397/04/08

Registrant information

Name

Mahdieh Ebrahimzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5543 1083

Email address

ebrahimzadehm6@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of probiotic capsule on prevention of gestational diabetes in high risk pre-diabetic pregnant women

Public title
The effect of probiotic capsule on prevention of gestational diabetes

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate; Reading and writing literacy; Earn Minimum 2 score of 20 score from the flowchart assess risk factors for gestational diabetes; Have a phone number, Being pre-diabetic, The gestational age between 14 and 16 weeks based on the first day of the last menstruation or the first trimester ultrasound; Normal screening tests for fetal abnormalities in the first stage; Single pregnancy; Fasting blood glucose less than 92 mg/dL and blood glucose two hours after food less than 120 mg/dL
Exclusion criteria:
History of allergy to cow's milk having a severe mental problem having a stressful incidence in the last 3 months smoking Having intention to termination of pregnancy Immune disorders Having a medical condition Pregnancy with in vitro fertilization Taking antibiotics continuously over the past 3 months

Age
From **16 years** old to **49 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: **243**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples were selected by convenient method and random allocation was done using statistical software in three groups (intervention, placebo, control).

Blinding (investigator's opinion)
Triple blinded

Blinding description
The same packaging and drug coding will be done by the pharmacist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the Mashhad Medical Science University

Street address

Mashhad, University Street, Quraishi Building

City

Mashhad

Province

Razavi Khorasan

Postal code

91735-951

Approval date

2018-05-08, 1397/02/18

Ethics committee reference number

IR.MUMS.REC.1397.039

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

Frequency of abnormal OGTT in three groups of probiotic users, placebo and control group

Timepoint

After 70 days of intervention at the end of the study

Method of measurement

Perform an OGTT blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Daily use of 1 pill of probiotic and get routine care

Category

Prevention

2

Description

Intervention group: Daily intake of 1 placebo and get routine care

Category

Prevention

3

Description

Control group: Get routine care according to the instructions of the Iranian Ministry of Health! Includes Exercise and Pregnancy Diet.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Health Center No. 3 of Mashhad

Full name of responsible person

Dr Brat Ali Arab Nejad

Street address

Khayyam Blvd., Ershad 8, St.Payam

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Phone

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Email

arabnejadba1@mums.ac.ir

Web page address

<http://behdasht3.mums.ac.ir>

2

Recruitment center

Name of recruitment center

Health Center No. 1

Full name of responsible person

Dr. Nasser Amini

Street address

Vakil Abad Boulevard, next to Urban City

City

Mashhad

Province

Razavi Khorasan

Postal code

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aminin1@mums.ac.ir

Web page address

<http://ch-mashhad1-mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samira Ebrahimzadeh

Street address

University of Nursing, Faculty of Nursing and Midwifery

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Ebrahimzadehzs@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mahdieh Ebrahimzadeh

Position

Graduate Student, Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

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ebrahimzadehm6@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Samira Ebrahimzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mahdieh Ebrahimzadeh

Position

Senior midwifery student

Latest degree

Master

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