

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of vaginal and oral probiotics in the prevention of preterm labor

Protocol summary

Study aim

Comparison of vaginal and oral probiotics in the prevention of preterm labor

Design

This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of 58 people in each group.

Settings and conduct

The study will be conducted at Kamali Hospital on pregnant women. Patients who signed informed consent will be randomly divided into three groups. The first group will receive probiotic tablets, daily from 25 weeks of pregnancy until 37 weeks of gestation. The second group will receive a probiotic vaginal capsule, daily from 25 weeks of pregnancy until 37 weeks of gestation, and the third group will not receive any intervention. The final outcome of the study will be assessed by a third party who is unaware of the study process. Also, the statistician will be unaware of the study process

Participants/Inclusion and exclusion criteria

Inclusion criteria: Intact amniotic membrane No taking probiotics No maternal disease including pyelonephritis, preeclampsia, chronic hypertension, diabetes. Gestational age greater than or equal to 25 weeks Normal cervical length exclusion criteria: The mother's unwillingness to be in this study Cervical length less than 3 cm Existence of labor show Effective labor pains Oligohydramnios polyhydramnios placental abruption placenta previa hepatic impairment Existence of abnormal fetal heart rate pattern in monitoring Intrauterine infection

Intervention groups

Intervention group1: Oral probiotic pills once a day for up to 37 weeks of pregnancy Intervention group2: Probiotic vaginal capsule once a day for up to 37 weeks of pregnancy Control group: No intervention

Main outcome variables

preterm labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201024049128N2**

Registration date: **2020-12-19, 1399/09/29**

Registration timing: **prospective**

Last update: **2020-12-19, 1399/09/29**

Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name

Bitra Badehnoosh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3222 2021

Email address

badehnoosh@abzums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of vaginal and oral probiotics in the prevention of preterm labor	
Public title	Comparison of probiotics in the prevention of preterm labor
Purpose	Prevention
Inclusion/Exclusion criteria	Inclusion criteria: Intact amniotic membrane No taking probiotics No maternal disease including pyelonephritis, preeclampsia, chronic hypertension, diabetes. Gestational age greater than or equal to 25 weeks Normal cervical length Exclusion criteria: The mother's unwillingness to be in this study Cervical length less than 3 cm Existence of labor show Effective labor pains Oligohydramnios polyhydramnios placental abruption placenta previa hepatic impairment Existence of abnormal fetal heart rate pattern in monitoring Intrauterine infection
Age	No age limit
Gender	Female
Phase	3
Groups that have been masked	- Investigator - Outcome assessor - Data analyser
Sample size	Target sample size: 185
Randomization (investigator's opinion)	Randomized
Randomization description	The randomization list will be prepared by the statistician (using the site: www. scale develope.com). Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained
Blinding (investigator's opinion)	Single blinded
Blinding description	Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind. Due to the type of intervention, participants will aware of the type of treatment
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Ethics committee unit; Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2020-12-12, 1399/09/22

Ethics committee reference number

IR.ABZUMS.REC.1399.222

Health conditions studied

1

Description of health condition studied

Preterm labor

ICD-10 code

O60

ICD-10 code description

Preterm labor

Primary outcomes

1

Description

Preterm labor

Timepoint

Delivery before 37 weeks

Method of measurement

Medical record

Secondary outcomes

1

Description

Kind of delivery

Timepoint

After labor

Method of measurement

Medical record

2

Description

NICU administration

Timepoint

After birth

Method of measurement

Medical record

Intervention groups**1****Description**

Intervention group: Oral probiotic pills once a day for up to 37 weeks of pregnancy

Category

Prevention

2**Description**

Intervention group: Probiotic vaginal capsule once a day for up to 37 weeks of pregnancy

Category

Prevention

3**Description**

Control group: No intervention

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kamali hospital

Full name of responsible person

Bita Badehnoosh

Street address

Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street

City

Karaj

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3149779453

Phone

+98 26 3222 2021

Email

b_badehnoosh@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Nourisepehr

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Research@abzums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Karaj 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**

Karaj University of Medical Sciences

Full name of responsible person

Bita badehnoosh

Position

Assistant Professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Karaj University of Medical Sciences
Full name of responsible person
Bita badehnoosh
Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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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