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
Bita 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
Province
Alborz
Postal code
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
Street address
Vice Chancellor for Research; No.20; Saffarian alley; 45 Metri Golshahr street
City
Karaj
Province
Alborz
Postal code
3198764653
Phone
+98 26 3464 3705
Email
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
Kamali hospital; Kamali alley; Shohada square; Shahid Beheshti street
City
Karaj
Province
Alborz
Postal code
3149779453
Phone
+98 26 3222 2021
Email
b_badehnoosh@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person
Bita badehnoosh

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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

City
Karaj

Province
Alborz

Postal code
3149779453

Phone
+98 26 3222 2021

Email
b_badehnoosh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Bita Badehnoosh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Shahid beheshti St., Shohada Sq., kamali Aly, Kamali hospital

City
Karaj

Province
Alborz

Postal code
3149779453

Phone
+98 26 3222 2021

Fax

Email
badehnoosh@abzums.ac.ir

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