Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of oral probiotics on the prevention of preterm delivery in mothers at risk of preterm delivery compared with placebo

Protocol summary

Study aim
Evaluation of oral probiotics on prevention of preterm delivery in mothers at risk of preterm delivery compared with placebo

Design
clinical trial with control group; With Parallel groups; randomized; design of 120 patients

Settings and conduct
Eligible patients entering the study referred to Imam Sajjad Hospital of Yasuj University of Medical Sciences will be divided into two groups of 60 people and the consequences of pregannncy will be measured.

Participants/Inclusion and exclusion criteria
Patient age 18-45 years, gestational age between 16-24 weeks, absence of syphilis, gonorrhea and HIV clinically, having risk factors for preterm delivery in the current pregnancy, including a history of preterm, delivery or a second trimester abortion in a previous pregnancy, no elective or emergency cerclage, lack of maternal insulin-dependent diabetes mellitus, treatment of hypertension, lupus, no clinical chorioamnionitis

Intervention groups
Group A : Lactofem capsule (500 mg) made by Iranian zist-takhmir Company will be administered orally and daily from the 16 weeks until the end of pregnancy.
Group B : Placebo drug is very similar to group A with the same method, the duration of treatment will be prescribed. The placebo drug will be prepared by a zist-takhmir company similar to probiotics. In both groups, intramuscular injection of 250 mg of 17 alpha hydroxy progesterone caproate will be given intramuscularly from 16 weeks to 37 weeks of pregnancy.

Main outcome variables
Premature preterm birth (less than 34 weeks gestation), late preterm birth (34-37 weeks gestation)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201108049300N1**
Registration date: **2021-10-02, 1400/07/10**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-02, 1400/07/10**
Update count: **0**

Registration date
2021-10-02, 1400/07/10

Registrant information

Name
Mansooreh Sangchooli moghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 74 3322 0165

Email address
parsatop007@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-18, 1400/06/27

Expected recruitment end date
2022-05-20, 1401/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of oral probiotics on the prevention of preterm delivery in mothers at risk of preterm delivery compared with placebo

Public title
Effect of oral probiotics on the prevention of preterm delivery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient age 18-45 years Gestational age between 16-24 weeks Absence of syphilis, gonorrhea and HIV clinically Having risk factors for preterm delivery in the current pregnancy, including a history of preterm delivery or a second trimester abortion in a previous pregnancy No elective or emergency cerclage Lack of maternal insulin-dependent diabetes mellitus, treatment of hypertension, lupus
Exclusion criteria:
Reluctance to participate in the study Failure to complete the course of treatment or use of probiotics Taking drugs that affect the intestinal microbial flora, such as antibiotics Occurrence of any genital or urinary tract infection requires antibiotic treatment during treatment Fetus with congenital malformations and abnormal scan anomalies Clinical chorioamnionitis
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization process is done with Random Allocation Soft ware. Randomization is done using the block method. It is an individual randomization unit. Randomization is performed using a table of random numbers and a computer is used to generate a random sequence online. To hide the treatment allocation, the list of treatments is placed in sealed and numbered envelopes (to maintain sequence order).
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yasuj University of Medical Sciences
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, kohgiluyeh and boyer-ahmad
City
yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7916839319
Approval date
2020-09-23, 1399/07/02
Ethics committee reference number
IR.YUMS.REC.1399.132

Health conditions studied

1

Description of health condition studied
preterm delivery
ICD-10 code
O60.1
ICD-10 code description
Preterm labor with preterm delivery

Primary outcomes

1

Description
Premature preterm birth (less than 34 weeks gestation)
Timepoint
End of intervention
Method of measurement
Symptom

2

Description
Late preterm birth (34-37 weeks gestation)
Timepoint
End of intervention
Method of measurement
Symptom

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Lactofem capsule (500 mg) made by Iranian zist-takhmir Company will be administered orally and daily from the 16 weeks until the end of pregnancy.
Category
Treatment - Drugs

2

Description
Control group: Placebo drug is very similar to group A with the same method, the duration of treatment will be prescribed. The placebo drug will be prepared by a zist-takhmir company similar to probiotics.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasuj University of Medical Sciences
Full name of responsible person
Raziyeh Vanda
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Sponsors / Funding sources

1

Sponsor
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oryad.hossein@yums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yasouj 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
Yasouj University of Medical Sciences
Full name of responsible person
Raziyeh Vanda
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available