Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of oral probiotics on pregnancy outcomes in pregnant women undergoing cerclage compared with placebo

Protocol summary

Study aim
Evaluation of the effect of oral probiotics on pregnancy outcomes in pregnant women undergoing cerclage compared with placebo

Design
clinical trial with control group; With Parallel groups; One blinded; randomized; design of 104 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 52 people and the consequences of pregannncy will be measured.

Participants/Inclusion and exclusion criteria
Patient age 18-45 years Gestational age between 14-24 weeks Cerclage by McDonald method Absence of syphilis, gonorrhea and HIV clinically Single pregnancy Lack of maternal insulin-dependent diabetes mellitus, treatment of hypertension, lupus No clinical chorioamnionitis Desire to participate in the study Any genital or urinary tract infection requires antibiotic treatment during treatment

Intervention groups
Group A (cerclage plus lactofem): Lactofem capsule (500 mg) made by Iranian zist-takhmir Company will be administered orally and daily from the day of cerclage until the end of pregnancy. Group B (cerclage with placebo): 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.

Main outcome variables
Premature preterm birth (less than 34 weeks gestation), late preterm birth (34-37 weeks gestation), premature rupture of amniotic sac, type of delivery (normal and cesarean section)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160524028038N11**
Registration date: **2021-04-29, 1400/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-04, 1401/09/13**
Update count: **1**

Registration date
2021-04-29, 1400/02/09

Registrant information

Name
Fatemeh Bazarganipour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3366 6367

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bazarganipour@hums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-24, 1399/07/03

Expected recruitment end date
2021-09-11, 1400/06/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of oral probiotics on pregnancy outcomes in pregnant women undergoing cerclage compared with placebo

Public title
Oral probiotics and cerclage
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient age 18-45 years Gestational age between 14-24 weeks Cerclage by McDonald method Absence of syphilis, gonorrhea and HIV clinically Single pregnancy Lack of maternal insulin-dependent diabetes mellitus, treatment of hypertension, lupus No clinical chorioamnionitis
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
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: **104**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software; Sequence Building: Using randomized in 4 blocks; Hiding method: Use envelopes in the package
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.1399.130

Health conditions studied

1

Description of health condition studied
Cervical insufficiency
ICD-10 code
O00-O08
ICD-10 code description
Pregnancy with abortive outcome

Primary outcomes

1

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

2

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

3

Description
Premature rupture of amniotic sac,
Timepoint
End of intervention
Method of measurement
Questionnaire

4

Description
Type of delivery (normal and cesarean section)
Timepoint
End of intervention
Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

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

2

Description
Control group (cerclage with placebo): 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 Medicinal Plants Laboratory, Yasouj University of Medical Sciences similar to probiotics.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yasuj University of Medical Sciences
Full name of responsible person
Raziyeh Vanda
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Hossein Mari-Oriad
Street address
No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad
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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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Person responsible for scientific inquiries

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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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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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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