

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 pregnancy 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)

Phone

+98 76 3366 6367

Email address

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

Kohgiluyeh-va-Boyerahmad

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

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No. 7916839319, Shahid Jalil Ave., Yasuj Town, Kohgiluyeh and Boyer-Ahmad

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f.bazarganipour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasouj University of Medical Sciences

Full name of responsible person

Hossein Mari-Oriad

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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

Contact

Name of organization / entity

Iran 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 updating data

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Name of organization / entity

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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