

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of probiotic vaginal with conventional treatment on delivery outcome and pro inflammatory cytokine levels in patients with premature rupture of fetal membranes

Protocol summary

Study aim

The aim of this study was to evaluate the effect of vaginal probiotic administration on labor outcome and proinflammatory cytokine levels in patients with premature rupture of membranes.

Design

Clinical trial with placebo control group, with parallel groups, double blind, on 108 patients

Settings and conduct

This double-blind clinical trial study will be performed in Besat Hospital, Sanandaj University of Medical Sciences, Iran. The experiment is planned in such a way that neither the subjects nor the observers know who is in which group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant mothers 20 to 40 years old with P-PROM without risk factor. Non-inclusion criteria: body mass index equal to or greater than 29; metabolic diseases; uterine abnormalities; patients with cervical insufficiency and patients with assisted reproductive techniques

Intervention groups

Group 1: (Negative control) Healthy mothers who will receive 3 cc of intravenous blood on the day of delivery three hours before delivery. Group 2: (Positive control): Patients with premature rupture of the membrane for whom the usual treatment of P-PROM will be performed. Group 3: (Intervention): Patients with premature rupture of the membrane for whom the usual P-PROM treatment will be performed, as well as daily adjuvant therapy with vaginal probiotic pills for 10 days will be prescribed.

Main outcome variables

Glucose, insulin, testosterone, SHBG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200921048790N1**

Registration date: **2020-10-19, 1399/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-19, 1399/07/28**

Update count: **0**

Registration date

2020-10-19, 1399/07/28

Registrant information

Name

Nasrin Soufizade

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3315 3574

Email address

sciences1398@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-06, 1399/07/15

Expected recruitment end date

2021-03-05, 1399/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of probiotic vaginal with

conventional treatment on delivery outcome and pro inflammatory cytokine levels in patients with premature rupture of fetal membranes

Public title

The effect of vaginal probiotic on perinatal outcome in patient with premature rupture of fetal membranes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant mothers 20 to 40 years old with P-PROM without risk factor

Exclusion criteria:

Body mass index equal to or greater than 29 Metabolic diseases Uterine abnormalities, Patients with cervical insufficiency Pregnancy with assisted reproductive techniques

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method is based on random blocks of size 4 and the blocks are as following: BABA BBAA ABAB AAB B ABBA BAAB BABA BBAA BABA ABBA BABA BBAA ABAB AAB B ABBA BAAB BABA BBAA BABA ABBA BBAA ABAB BABA ABBA BAAB

Blinding (investigator's opinion)

Double blinded

Blinding description

In double-blind placebo studie: For blinding, placebo will be used in shape, color and smell similar to the main drug

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Commission of Kurdistan University of Medical Sciences

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6615685156

Approval date

2020-05-23, 1399/03/03

Ethics committee reference number

IR.MUK.REC.1399.037

Health conditions studied

1

Description of health condition studied

premature rupture of fetal membranes

ICD-10 code

O42

ICD-10 code description

premature rupture of fetal membranes

Primary outcomes

1

Description

Glucose

Timepoint

Day of delivery

Method of measurement

ELISA kit

2

Description

Insulin

Timepoint

day of delivery

Method of measurement

Elysa kit

3

Description

Testosterone

Timepoint

Day of delivery

Method of measurement

Elysa kit

4

Description

SHBG

Timepoint

Day of delivery

Method of measurement

Elysa kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with premature rupture of the membrane for whom the usual P-PROM treatment will be performed, as well as daily adjuvant therapy and vaginal probiotic pills for 10 days will be prescribed.

Category

Treatment - Drugs

2

Description

Positive control: Patients with premature rupture of the membrane for whom the usual P-PROM treatment and placebo will be performed.

Category

Treatment - Drugs

3

Description

Control group (Negative control): Healthy mothers who receive a placebo. Three cc of intravenous blood will be received from them 3 hours before delivery on the day of delivery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital, Kurdistan University of Medical Sciences, Sanandaj, Iran

Full name of responsible person

Nasrin Soufizade

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6615685156

Phone

+98 87 3315 3574

Email

soofizadehn@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Afshin Maleki

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6615685156

Phone

+98 87 3336 4645

Email

muk@ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Nasrin Soufizade

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6615685156

Phone

+98 87 3315 3574

Email

soofizadehn@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Nasrin Soufizade

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6615685156

Phone

+98 87 3315 3574

Email

soofizadehn@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Nasrin Soufizade

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Pasdaran

City

Sanandaj

Province

Kurdistan

Postal code

6615685156

Phone

+98 87 3315 3574

Email

soofizadehn@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

2021

To whom data/document is available

researcher

Under which criteria data/document could be used

All

From where data/document is obtainable

Responsible author

What processes are involved for a request to access data/document

Send an email to nasrin.soufi2020@gmail.com

Comments