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
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Iran (Islamic Republic of)
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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 AABB ABBA BAAB BABA BBAA BABA ABBA BABA BBAA ABAB AABB 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
Testostrone
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sanandaj University of Medical Sciences
Full name of responsible person
Afshin Maleki
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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
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Person responsible for updating data

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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