Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Determining the effect of vaginal probiotics on perinatal outcomes in women with premature rupture of membranes

Protocol summary

Study aim
The Determining the effect of vaginal probiotics on perinatal outcomes in women with premature rupture of membranes

Design
In a randomized clinical trial with the parallel control group,single -blind; Phase 2-3, on 106patients; randomization is performed by using block randomization

Settings and conduct
A single-blind parallel clinical trial study will be conducted on 106 women with premature rupture of fetal membranes at Fatemieh Hospital in Hamedan. The researcher who measures and records the outcomes is unaware of the type of intervention performed, so the study is conducted as a single-blind study

Participants/Inclusion and exclusion criteria
Inclusion criteria : Single live pregnancy;Gestational age between 24 and 34 weeks with premature rupture of fetal membranes;no evidence of fetal distress,no vaginal bleeding,no symptoms of chorioamnionitis. Exclusion criteria: Active labor;Symptoms of vaginal infection;Fetal congenital abnormalities;individuals who give birth within the first 48 hours of hospitalization;High blood pressure;Diabetes;Fetal growth restriction, and fetal

Intervention groups
Intervention group: Women with premature rupture of membranes are prescribed intravenous ampicillin 2 grams every 6 hours and then 500 milligrams of amoxicillin capsules every 8 hours for 5 days, as well as one gram of oral azithromycin tablets. In addition, vaginal probiotics from the Lactovazh brand by Biostakmir Company containing Lactobacillus rhamnosus (CU 109+Inulin) are given for two week. Control group: Only antibiotic therapy with the same intervention protocol is given to control group patients.”

Main outcome variables
Gestational age, birth weight, Apgar score, type of delivery, duration of neonatal hospitalization, neonatal sepsis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N30**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**
Update count: **0**

Registration date
2024-01-17, 1402/10/27

Registrant information

Name
Mohammad Faryadras

Name of organization / entity
Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 81 3428 9706

Email address
m.faryadras@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date
2024-05-19, 1403/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Determining the effect of vaginal probiotics on perinatal outcomes in women with premature rupture of membranes

Public title
The Determining the effect of vaginal probiotics on perinatal outcomes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Single live pregnancy Gestational age between 24 and 34 weeks with premature rupture of fetal membranes No evidence of fetal distress No vaginal bleeding No symptoms of chorioamnionitis

Exclusion criteria:
Active labor Symptoms of vaginal infection Fetal congenital abnormalities, individuals who give birth within the first 48 hours of hospitalization. High blood pressure Diabetes Fetal growth restriction, and fetal

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked

- Investigator

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will randomly assign the cases to intervention and control groups. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are removed. The four paper sheets will be then placed back into the container, and this action will be repeated until the sample size is reached.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person who examines patients for outcomes is not informed of the allocation of patients to the intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Science

Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2023-12-30, 1402/10/09

Ethics committee reference number
IR.UMSHA.REC.1402.622

Health conditions studied

1

Description of health condition studied
Preterm spontaneous labour with term delivery

ICD-10 code
O60.2

ICD-10 code description
Preterm spontaneous labour with term delivery

Primary outcomes

1

Description
Gestational age

Timepoint
Delivery time

Method of measurement
By the date of the first day of the last period and ultrasound

2

Description
The time interval between the rupture of the membranes and the onset of labor

Timepoint
Delivery time

Method of measurement
The length of delay per day is calculated by subtracting the delivery time from the membrane rupture time.

Secondary outcomes

1

Description
Birth weight
Timepoint
post partum
Method of measurement
Using a digital scale

2

Description
Apgar score
Timepoint
after delivery
Method of measurement
documented data

3

Description
chorioamnionitis
Timepoint
after delivery
Method of measurement
documented data (will be determined by clinical symptoms, including fever and tachycardia)

4

Description
Neonatal sepsis
Timepoint
after delivery
Method of measurement
documented data(by blood culture)

5

Description
Type delivery
Timepoint
after delivery
Method of measurement
Cesarean section - vaginal normal delivery

Intervention groups

1

Description
Intervention group: Women with premature rupture of membranes are prescribed intravenous ampicillin 2 grams every 6 hours and then 500 milligrams of amoxicillin capsules every 8 hours for 5 days, as well as one gram of oral azithromycin tablets. In addition, vaginal probiotics from the Lactovazh brand by Biostakmir Company containing Lactobacillus rhamnosus (CU 109+Inulin) are given for two week.
Category
Treatment - Drugs

2

Description
Control group: Women with premature rupture of membranes are prescribed intravenous ampicillin 2 grams every 6 hours and then 500 milligrams of amoxicillin capsules every 8 hours for 5 days, as well as one gram of oral azithromycin tablets.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Hamidhe Parsapour
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 912 390 5645
Email
h.parsapour@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Reza Shokohei
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh street
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
vc_research@umsha.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Hamidhe Parsapour

Position
Assistant profrssor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Fatemieh Hospital, Pasdaran Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0717

Email
h.parsapour@umsha.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Shadi Ghane Fard

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Fatemieh Hospital, Pasdaran Ave.

City
Hamadan

Province
Hamadan

Postal code
6514845411

Phone
+98 901 945 0846

Email
shadifgf60@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Shadi Ghane Fard

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Fatemieh Hospital, Pasdaran Ave.

City
Hamadan

Province
Hamadan

Postal code
6517838695

Phone
+98 81 3838 0717

Email
shadifgf60@gmail.com

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
There is not a plan to make this available

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