

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jun 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 106 patients; 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 Fatemeh 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 weeks. 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 profrrsor
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