Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2026

Investigation of the effects of vaginal probiotic capsules on prolonging the time of membrane rupture up to delivery and on maternal and fetal complications.

Protocol summary

Study aim

Investigation of the effects of vaginal probiotic capsules on prolonging the time of membrane rupture up to delivery and on maternal and fetal complications

Design

In this study, 64 pregnant women who have the inclusion criteria and refer to Ghaem, Emam Reza and Ommolbanin hospitals are chosen. Participants are randomly divided to intervention and control group (Randomization is done by computer).

Settings and conduct

Regarding that the most important factor in neonatal death is Preterm delivery, and on the other hand the reason of 35 percent of these Preterm delivery is preterm membrane rupture and also due to the fact that after delivery, the more the age, the less the complications related to preterm infant, in this study. Therefore, with the prescription of vaginal probiotic capsules and maintaining normal vaginal microbial flora, it is aimed to increase pregnancy age and reduce the complications of being preterm. This study will be carried out in Ghaem, Emam Reza and Ommolbanin hospitals in Mashhad. No blinding is done and patients are randomly divided to two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: live singleton pregnancy, being pregnant for 24 to 32 weeks, no symptoms of chorioamniotic, no sign of fetal distress, no vaginal bleeding, consent of mothers to participate in the study. Exclusion criteria: sings of chorioamniotic, disturbed fetal health assessment test, vaginal bleeding, unwillingness of patients to continue participating in the study.

Intervention groups

for randomization, two equal sets of green and blue cards are provided and placed in envelopes (Randomization is done by computer). An envelope will be allocated to each patient. In both green and blue groups, the awaiting treatment is carried out as following: In the first 48 hours of hospitalization, 2 grams of intravenous Ampicillin injection per 6 hours and then for a week, 500-milligram Amoxicillin capsules per 8 hours and 400-milligram Erythromycin pills per 6 hours are prescribed. Also two doses of 12-milligram intramuscular Betamethasone injection within 24 hours is prescribed. Mother's vital signs and fetus health are precisely controlled through daily NST, sonography twice a week and CBC every other day. Additionally for patients who have green sets of cards, during this period of time, one vaginal probiotic capsule made by ZIST TAKHMIR company is prescribed daily for 10 days.2 weeks after delivery, infants and mothers in both groups will be still be followed.

Main outcome variables

Main outcomes: duration of awaiting treatment and pregnancy age at the time of delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020264N3**
Registration date: **2018-03-19, 1396/12/28**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-19, 1396/12/28**
Update count: **0**

Registration date

2018-03-19, 1396/12/28

Registrant information

Name

Seyedeh Azam Pourhoseini

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-10-23, 1396/08/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of the effects of vaginal probiotic capsules on prolonging the time of membrane rupture up to delivery and on maternal and fetal complications.

Public title
Investigation of the effects of vaginal probiotic capsules on prolonging the time of membrane rupture up to delivery and on maternal and fetal complications.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
live singleton pregnancy being pregnant for 24 to 32 weeks no symptoms of chorioamniotic no sign of fetal distress no vaginal bleeding consent of mothers to participate in the study

Exclusion criteria:
sings of chorioamniotic disturbed fetal health assessment test vaginal bleeding unwillingness of patients to continue participating in the study

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
for randomization, two equal sets of green and blue cards are provided and placed in envelopes (Randomization is done by computer). An envelope will be allocated to each patient.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

City
Mashhad

Province
Razavi Khorasan

Postal code
9176699199

Approval date
2017-09-27, 1396/07/05

Ethics committee reference number
IR.MUMS.REC.1396.194

Health conditions studied

1

Description of health condition studied
prevention of Preterm delivery and maternal and fetal complications

ICD-10 code
060.0

ICD-10 code description
Preterm labour without delivery

Primary outcomes

1

Description
prolonging the time of membrane rupture up to 34 weeks

Timepoint
Precise control of mother's vital signs and fetus health, two times of sonography during a week and CBC every other day

Method of measurement
Fetus health is evaluated through NST.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: for pregnant women with premature membrane rupture, in the first 48 hours of hospitalization, 2 grams of intravenous Ampicillin injection per 6 hours and then for a week, 500-milligram Amoxicillin capsules per 8 hours and 400-milligram Erythromycin pills per 6 hours are prescribed. Also two doses of 12-milligram intramuscular Betamethasone injection within 24 hours is prescribed. Mother's vital signs and fetus health are precisely controlled through daily NST, sonography twice a week and CBC every other day. Additionally during this period of time, one vaginal probiotic capsule made by ZIST TAKHMIR company is prescribed daily for 10 days.

Category

Treatment - Drugs

2

Description

Control group: for pregnant women with premature membrane rupture, in the first 48 hours of hospitalization, 2 grams of intravenous Ampicillin injection per 6 hours and then for a week, 500-milligram Amoxicillin capsules per 8 hours and 400-milligram Erythromycin pills per 6 hours are prescribed. Also two doses of 12-milligram intramuscular Betamethasone injection within 24 hours is prescribed. Mother's vital signs and fetus health are precisely controlled through daily NST, sonography twice a week and CBC every other day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam Reza hospital

Full name of responsible person
Mahnoush Rohizadeh

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Emam Reza hospital, Emam Reza Sq, Ebne-Sina Ave

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2

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
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3

Recruitment center

Name of recruitment center
Ommol-Banin hospital

Full name of responsible person
Mahnoush Rohizadeh

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Ommol-Banin hospital, Azadi 16th, Azadi Avenue

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person
Dr Mohsen Tafaghodi

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Grant name

Grant code / Reference number
951811
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
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Full name of responsible person
Seyedeh Azam Pourhoseini
Position
Assistant Professor
Latest degree
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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
All data can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

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

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments