Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Investigation of maternal and neonatal outcomes of expectant treatment in pregnant women with preterm premature rupture of membranes (PPROM) in hospital compared with expectant treatment at home

Protocol summary

Study aim
Investigation of maternal and neonatal outcomes of expectant treatment in pregnant women with PPROM in hospital compared with expectant treatment at home

Design
Expectant treatment for both groups is as follows: in the first 72 hours of hospitalization, 2 grams of intravenous ampicillin in every 6 hours, 500 milligram amoxicillin capsule in every 8 hours and 400 milligram erythromycin tablet in every 6 hours are prescribed for a week. Two doses of 12 milligram Betamethasone are prescribed for intramuscular injection with a 24-hour interval in between. Accurate monitoring of the mother's vital signs, an assessment of the fetus health with daily NST and sonoghraphy and CBC twice a week are carried out. The mothers under surveillance at home monitor and record their daily fever and pulse rate and Patients are recommend to carry out NST simultaneously with CBC twice a week.

Settings and conduct
Assigning individuals to groups depends on their personal preferences for staying at home or hospital based on which the study is divided into two groups. Outpatients are those who knowingly and willingly discharge themselves and will be placed under surveillance at home.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Gestational age between 25 and 34 weeks, Evaluation for 72 hours in hospital, Having a caretaker at home, taking 60 minutes at most to reach the first treatment center. Exclusion criteria: Occurrence of chorioamnionitis, fetal tests of health evaluation, Vaginal bleeding

Intervention groups
Control group: After receiving expectant treatment, patients are hospitalized until delivery. Intervention group: After receiving the expectant treatment, patients will be at home until delivery.

Main outcome variables
Duration of expectant treatment, gestational age at time of delivery, birth weight, number of cesarean section

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181115041666N1**
Registration date: **2018-12-26, 1397/10/05**
Registration timing: **prospective**

Last update: **2018-12-26, 1397/10/05**
Update count: **0**

Registration date
2018-12-26, 1397/10/05

Registrant information

Name
Samaneh Akbarzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3801 2806

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-25, 1398/02/05

Expected recruitment end date
2019-04-25, 1398/02/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of maternal and neonatal outcomes of expectant treatment in pregnant women with preterm premature rupture of membranes (PPROM) in hospital compared with expectant treatment at home

Public title

Comparison of expectant treatment outcomes in pregnant women with preterm premature rupture of membranes (PPROM) at home and hospital

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

alive singleton pregnancy Gestational age between 25 and 34 weeks The absence of chorioamnionitis symptoms The lack of evidence for fetal distress No vaginal bleeding Patient's consent Evaluation for 72 hours in hospital Cephalic presentation Having a caretaker at home Taking 60 minutes at most to reach the first treatment center The diameter of maximum vertical pocket of the amniotic fluid is more than 2 Cm^2

Exclusion criteria:

Occurrence of chorioamnionitis disturbed fetal tests of health evaluation Vaginal bleeding Patient's unwillingness to continue participation in the study Gestational age of less than 25 weeks of labor (greater than 3 cm of dilatation)

Age

No age limit

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

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

2018-01-03, 1396/10/13

Ethics committee reference number

IR.MUMS.fm.REC.1396.640

Health conditions studied

1

Description of health condition studied

preterm premature rupture of membranes

ICD-10 code

O42

ICD-10 code description

Premature rupture of membranes

Primary outcomes

1

Description

Duration of expectant treatment course

Timepoint

From hospitalization to delivery

Method of measurement

duration in days

2

Description

gestational age at the time of delivery

Timepoint

at the time of birth

Method of measurement

Course duration is measured based on the number of weeks.

3

Description

Birth weight

Timepoint

at the time of child birth

Method of measurement

using scales

4

Description
number of cesarean section
Timepoint
Time of birth
Method of measurement
number of cesarean section in each group

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Expected treatment is that in the first 72 hours of hospitalization, 2 milligrams of intravenous ampicillin in every 6 hours, 500 milligram amoxicillin capsule in every 8 hours and 400 milligram erythromycin tablet in every 6 hours are prescribed for a week. Two doses of 12 milligram Betamethasone are prescribed for intramuscular injection with a 24-hour interval in between, and accurate monitoring of the mother's vital signs, an assessment of the fetus health with daily NST and ultrasound twice a week and CBC twice a week are carried out.
Category
Treatment - Drugs

2

Description
Intervention group: After 72 hours of hospitalization and receiving the expectant treatment, mothers go home with their consent and monitor and record their daily fever and pulse rate (twice a day) and in the event of any disorder, they will immediately refer to the hospital. The executor of the plan will provide the patients under surveillance with his/her phone number and monitor their vital signs through making phone calls or sending messages in Telegram. Patients are recommend to carry out NST simultaneously with CBC twice a week.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ommol-Banin hospital
Full name of responsible person
Masoumeh Mirteimouri
Street address
Ommol-Banin hospital, Azadi 16th, Azadi Avenue
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9144663595
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mirteimourim@mums.ac.ir

2

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Samaneh Akbarzadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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345 - 91357
Phone
+98 51 3841 2081
Email
ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
960209
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

Mashhad University of Medical Sciences

Full name of responsible person

Samaneh Akbarzadeh

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Masoumeh Mirteimouri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Name of organization / entity

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Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable

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