

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of a complete course of betamethasone on neonatal and mothers with Premature rupture of membranes at 34 to 36 weeks of pregnancy

Protocol summary

Study aim

Assessing the efficacy of Betamethasone in pregnant women with PROM at 34 to 36 week of gestational age

Design

A randomized clinical trial with a parallel control group, phase 3, 100 patients in each group; Randomization using the random numbers table.

Settings and conduct

In Mahdieh hospital in Tehran, eligible pregnant women will be divided into intervention and control groups with simple randomization technique using a table of random numbers. In 100 women in the intervention group, 12 mg of betamethasone will be injected intramuscularly on the first day and another 12 mg 24 hours later. Betamethasone will not be injected in 100 women the control group. The outcomes related to mother and baby in these two groups will be followed up and recorded. Concealment is not possible for the patient and the researcher in terms of the type of intervention, and only the data collection and information analysis group will be unaware of the placement of the patient in the test or control group.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: PROM at 34 to 36 week of GA; single gestation. Exclusion Criteria: Chorioamnionitis; 48 hours passed from the rupture of the membrane; maternal fever; maternal tachycardia; indication for emergency termination of pregnancy; maternal diabetes; no consent for being in this research.

Intervention groups

Intervention group: Pregnant women with PROM at 34 to 36 week of GA who will receive Betamethasone Control group: Pregnant women with PROM at 34 to 36 week of GA who will not receive Betamethasone

Main outcome variables

Neonatal Respiratory Distress Score; Need for surfactant; Neonatal Mechanical Ventilation Days; Days of

hospitalization in neonates; Neonatal mortality rates during 28 days after birth; maternal infection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221010056141N1**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **prospective**

Last update: **2022-12-20, 1401/09/29**

Update count: **0**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Zahra Fahmfam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 2628

Email address

zahra.fahmfam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of a complete course of betamethasone on neonatal and mothers with Premature rupture of membranes at 34 to 36 weeks of pregnancy

Public title
Effect of Betamethasone in mothers with PROM

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Mothers with Premature rupture of membranes At 34 to 36 weeks of pregnancy Singleton pregnancy
Exclusion criteria:
 Symptoms of chorioamnionitis in mother: fever, tachycardia Infants small for gestational age Infants large for gestational age Any indication of emergency termination confirmed by fetal assessment Maternal diabetes Passing more than 48 hours from rupture of membrane

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization in such a way that the last digit of the patient file number is placed in the intervention group if it is even, and in the control group if it is odd.

Blinding (investigator's opinion)
Single blinded

Blinding description
data collection and information analysis group will be unaware of the placement of the patient in the test or control group. The primary data will be provided to the data analysis group without mentioning the name of the group in the form of group A, B

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Research ethics Committees of School of Medicine- Shahid Beheshti University of Medical Sciences
Street address
 Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town, Tehran, Iran.
City
 Tehran
Province
 Tehran
Postal code
 1419943471
Approval date
 2022-06-07, 1401/03/17
Ethics committee reference number
 IR.SBMU.MSP.REC.1401.135

Health conditions studied

1

Description of health condition studied
Premature Rupture of Membrane

ICD-10 code
O42

ICD-10 code description
Premature rupture of membranes

Primary outcomes

1

Description
RDS Score

Timepoint
after birth of neonate

Method of measurement
Completion of RDS Score with inspection and auscultation

2

Description
APGAR Score

Timepoint
1 and 5 minute after birth

Method of measurement
inspection of neonate

3

Description
need for Surfactant administration

Timepoint
during first 3 day of life

Method of measurement
medical record of neonate

4

Description

maternal chorioamnionitis

Timepoint

since rupture of membrane till 48 hours after delivery,
every 6 hours

Method of measurement

existence of clinical signs : fever and tachycardia

Secondary outcomes

1

Description

local infection of mother

Timepoint

One week till one month after delivery. Daily during
hospitalization and weekly after discharge

Method of measurement

Observation of c section incision and perineum of mother
and assessment for infection signs

2

Description

neonatal death

Timepoint

28 days after birth

Method of measurement

neonatal medical record

Intervention groups

1

Description

Mothers with premature rupture of membrane between
34 to 36 weeks of gestational age, in which
betamethasone ampoule with a dose of 12 mg (3
ampoules of 4 mg at once) is injected intramuscularly
into the Gluteus muscle. 24 hours later, the second dose
will be repeated in the same way. Betamethasone
ampoule used is a product of Caspian Pharmaceutical
Company.

Category

Treatment - Drugs

2

Description

Control group: Pregnant women with premature rupture
of membrane that Betamethasone was not injected at 34
to 36 week of gestational age

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdijeh Hospital

Full name of responsible person

Zahra Naeiji

Street address

Rajab Nia St, Shishegar khane Ave, Fadaeiyan Eslam
St, Shoush Sq, Tehran

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mahdijeh_hospital@sbm.ac.ir

Web page address

<https://mmc.sbm.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo
Blvd, Velenjak, Tehran, Iran

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Phone

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Email

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Web page address

<https://sbm.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

1

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Naeiji

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available