

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparing of antenatal intramuscular administration of two doses of betamethasone every 12 hours with standard method every 24 hours on acute neonatal pulmonary complications in preterm infants born from women with preterm premature of membrane

Protocol summary

Summary

Objective: To determine the effect of two doses of betamethasone injections every 12 hours with the standard method every 24 hours on acute pulmonary complications in preterm infants born to mothers with gestational age of 26 to 34 weeks with PROM . Study Design: Randomized - Single blind - control by standard method - single centre . Study population: Pregnant women with a singleton pregnancy at the age of 26 to 34 weeks and premature rupture of membranes . Inclusion criteria:" Healthy women pregnant with singleton pregnancies and premature rupture of membranes at gestational age 26 to 34 weeks without the need for an immediate termination of pregnancy" . Exclusion criteria:" Presence of any increased blood pressure; diabetes ; intrauterine growth retardation; chorioamnionitis; fetal anomaly; fetal distress ; steroid use by mother and any disease that corticosteroids use are contraindicated" . Sample size : 156 patient. In intervention group : Antenatal intramuscular administration of two doses of 12 mg betamethasone every 12 hours for women with preterm premature of membrane . Control group : Antenatal intramuscular administration of two doses of 12 mg betamethasone every 24 hours for women with preterm premature of membrane . Study time: 2 years . Study outcome: Acute neonatal respiratory complications and Apgar score (first and fifth minute) of babies born after the last dose injection of betamethasone .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120415634N2**

Registration date: **2017-09-27, 1396/07/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-27, 1396/07/05

Registrant information

Name

Tayebeh Jahed Bozorgan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 6263

Email address

tayebe.jahed@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Preventive Gynecology Research Center of Imam Hossein Hospital

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing of antenatal intramuscular administration of

two doses of betamethasone every 12 hours with standard method every 24 hours on acute neonatal pulmonary complications in preterm infants born from women with preterm premature of membrane

Public title

The effect of antenatal intramuscular administration of two doses of betamethasone every 12 hours on acute pulmonary complications in preterm infants born

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: " Healthy women pregnant with singleton pregnancies and premature rupture of membranes at gestational age 26 to 34 weeks without the need for an immediate termination of pregnancy" .
Exclusion criteria:" Presence of any increased blood pressure; diabetes ; chorioamnionitis ; intrauterine growth retardation; fetal anomaly; fetal distress ; steroid use by mother and any disease that corticosteroids use are contraindicated'.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **156**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

randomization by table of random number

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of the Shahid Behesti University of the Medical Sciences ,Theran , Iran

Street address

" SIDE OF AYATOLLAH TALEGANI HOSPITAL , SHAHID ARABI AVENUE , YAMAN AVENUE ,SHAHID CHAMRAN HIGHWAY "

City

Tehran

Postal code

1985717443

Approval date

2014-09-28, 1393/07/06

Ethics committee reference number

SBMU.REC.1393.308

Health conditions studied**1****Description of health condition studied**

Respiratory and cardiovascular disorders specific to the perinatal period

ICD-10 code

Respirator

ICD-10 code description

Hyaline membrane disease

Primary outcomes**1****Description**

Occurrence of Respiratory distress of newborn

Timepoint

First seven days of the neonatal period

Method of measurement

questionnaire

Secondary outcomes**1****Description**

APGAR

Timepoint

The first and fifth minutes after birth

Method of measurement

questionnaire

Intervention groups**1****Description**

Caspian tamin,Pharmaceutical Co.Rhast-IRAN,Betamethasone 4mg/ml .(In control group : Antenatal intramuscular two doses of 12 mg betamethasone every 24 hours administer to women with preterm premature of membrane) .

Category

Treatment - Drugs

2**Description**

Caspian tamin,Pharmaceutical Co.Rhast-IRAN,Betamethasone 4mg/ml . (In intervention group : Antenatal intramuscular two doses of 12 mg betamethasone every 12 hours administer to women

with preterm premature of membrane) .

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mahdiyeh Hospital

Full name of responsible person

parisa hashemi

Street address

" Fadaian Eslam Highway; Shoush squire"

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Imam Hossein Hospital ; Preventive Gynecology
Research Center

Full name of responsible person

Farah farzaneh

Street address

Madani street ; Imam Hossein Hospital

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Imam Hossein Hospital ; Preventive Gynecology
Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Mahdiyeh Hospital

Full name of responsible person

Parisa Hashemi

Position

Resident of Obstetric & Gynecology

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

tayebeh Jahed Bozorgan

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Assistant Professor

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Madiyeh Hospital

Full name of responsible person

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Position

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City

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty