Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Sep 2026

Comparing of antenatal intramuscular adminestration 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 adminestration of two doses of 12 mg betamethasone every 12 hours for women with preterm premature of membrane . Control group : Antenatal intramuscular adminestration 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 adminestration 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 ofantenatal intramuscular adminestration 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 squre"

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

FADAIAN ISLAM HIGH WAY ,SHOOSH SQUARE

City

Tehran

Postal code

Phone

+98 21 5506 6263

Fax

Email

parisahashemi62@yahoo.com

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

Position

Assistant Professor

Other areas of specialty/work

Street address

Mahdiyeh Hospital

City

Tehran

Postal code

Phone

+98 21 5506 6263

Fax

Email

tayebeh.jahed@yahoo.com;tayebe.jahed@sbmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Madiyeh Hospital

Full name of responsible person

Parisa Hashemi

Position

Resident of Obstetric & Gynecology

Other areas of specialty/work

Street address

" FADAIAN ISLAM HIGH WAY , SHOOSH SQUARE "

City

Tehran

Postal code

Phone

+98 21 5506 6263

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