Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A comparison between the efficacy of intravascular betamethasone phosphate versus intra muscular betamethasone phosphate on neonates in the cases of emminant preterm birth.

Protocol summary

Summary

Objective: A comparison between the efficacy of intravascular betamethasone phosphate versus intra muscular betamethasone phosphate on neonates in the cases of emminant preterm birth. Design: double blind randomized clinical trial. Setting and conduct: Eligible women will be randomly assigned in the two groups of A and B. In group A, 12 mg intra muscular betamethasone phosphate and in group B, 12 mg slow IV betamethasone phosphate will be prescribed . Participants:The women with eminent preterm labor. Inclusion criteria: estational age of 26-34 weeks; singleton pregnancy; cervical dilatation of equal or more than 3-4 cm and emminant preterm birth or delivery during less than 24 hours. Exclusion criteria: known allergy for betamethazone; history of any known maternal systemic disorders like hypertension, diabetes, liver and cardiac disease, renal failure and neoplasia. Intervention: In group A, 12 mg intra muscular betamethasone phosphate and in group B, 12 mg slow IV betamethasone phosphate will be prescribed . Main outcome measures: preterm neonates of the two groups will be compared according to respiratory distress syndrome, intra ventricular hemorrhage, necrotizing enterocolitis, neonatal sepsis, neonatal death, NICU admission, duration of NICU stay, and duration of maternal hospital stay.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201705052624N23**
Registration date: **2017-05-21, 1396/02/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the efficacy of intravascular betamethasone phosphate versus intra muscular betamethasone phosphate on neonates in the cases of emminant preterm birth.

Public title

A comparison between 2 administration rout of betamethasone on the neonates.

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: gestational age of 26-34 weeks; singleton pregnancy; cervical dilatation of equal or more than 3-4 cm and emminant preterm birth or delivery during less than 24 hours. Exclusion criteria: known allergy for betamethazone; history of any known maternal systemic disorders like hypertension, diabetes, liver and cardiac disease, renal failure and neoplasia.
Age
No age limit
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran.University of Medical Sciences
Street address
Hemmat highway, Chamran Cross
City
Tehran
Postal code
Approval date
2017-04-29, 1396/02/09
Ethics committee reference number
IR.IUMS.REC.1396.27410

Health conditions studied

1

Description of health condition studied
Preterm labor
ICD-10 code
060
ICD-10 code description
Preterm labour and delivery

Primary outcomes

1

Description
neonatal respiratory distress syndrome
Timepoint
After birth
Method of measurement
Data sheets

Secondary outcomes

1

Description
intra ventricular hemorrhage
Timepoint
After birth up to discharge.
Method of measurement
Data sheets

2

Description
necrotizing enterocolitis
Timepoint
After birth up to discharge.
Method of measurement
Data sheets

3

Description
neonatal death
Timepoint
After birth up to death,
Method of measurement
Data sheets

4

Description
NICU admission
Timepoint
After birth up to discharge.
Method of measurement
Data sheets

5

Description
duration of NICU admission.
Timepoint
After birth up to discharge.
Method of measurement
Data sheets

6

Description
neonatal sepsis.
Timepoint
After birth up to discharge.
Method of measurement
Data sheets

7

Description
maternal postpartum length of stay
Timepoint
After delivery up to discharge.
Method of measurement
Data sheets

Intervention groups

1

Description
In intervention group, prescription of 12 milligram betamethasone phosphate slow IV.
Category
Prevention

2

Description
In the control group, prescription of 12 milligram betamethasone phosphate intramuscularly.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbarabadi Teaching Hospital
Full name of responsible person
Maryam Kashanian
Street address
Molavi avenue, Molavi Cross Road.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research ,Iran University of Medical Sciences.
Full name of responsible person
Dr Seyed Ali Javad Mousavi
Street address
Hemmat High way, Junction of Chamran Highway.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research ,Iran University of Medical Sciences.
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
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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