

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

A comparison between the efficacy of intravascular betamethasone phosphate versus intra muscular betamethasone phosphate on neonates in the cases of eminent 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 eminent 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: gestational age of 26-34 weeks; singleton pregnancy; cervical dilatation of equal or more than 3-4 cm and eminent preterm birth or delivery during less than 24 hours. Exclusion criteria: known allergy for betamethasone; 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

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 3487

Email address

maryamka@iums.ac.ir

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 eminent 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 eminent 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

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor.

Other areas of specialty/work

Street address

Molavi avenue, Molavi Cross Road.

City

Tehran

Postal code

Phone

+98 21 5563 3244

Fax

Email

maryamkashanian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

MD.

Other areas of specialty/work

Street address

Molavi avenue, Molavi Cross Road.

City

Tehran

Postal code

Phone

+98 21 5563 3244

Fax
Email maryamkashanian@yahoo.com
Web page address

+98 21 5563 3244
Fax
Email
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Maryam Kashanian
Position
Professor
Other areas of specialty/work
Street address
Molavi Avenue, Molavi Cross Road.
City
Tehran
Postal code
Phone

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