

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

A comparison between the effect of the two methods of 12 versus 24 hours interval of betamethasone administration on neonatal respiratory distress syndrome in women with preterm labor. distress syndrome.

Protocol summary

Summary

Objective: A comparison between the effect of the two methods of 12 versus 24 hours interval of betamethasone administration on neonatal respiratory distress syndrome in women with preterm labor. Design: Method: 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, two doses of 12 mg betamethasone with the interval of 12 hours and in group B, two doses of 12 mg betamethasone with the interval of 24 hours will be prescribed. Participants: The women with preterm labor. Inclusion criteria: singleton pregnancy and gestational age of 26-34 weeks. 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, two doses of 12 mg betamethasone with the interval of 12 hours and in group B, two doses of 12 mg betamethasone with the interval of 24 hours will be prescribed. Main outcome measures: preterm neonates of the two groups will be compared according to respiratory distress syndrome, intra ventricular hemorrhage, retinopathy, necrotizing enter colitis, neonatal death, and NICU admission.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402072624N11**

Registration date: **2014-03-25, 1393/01/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-25, 1393/01/05

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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maryamka@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the effect of the two methods of 12 versus 24 hours interval of betamethasone administration on neonatal respiratory distress syndrome in women with preterm labor. distress syndrome.

Public title

Betamethasone administration in preterm labor.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: singleton pregnancy and gestational

age of 26-34 weeks. 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

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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Ghods Cross.

City

Tehran

Postal code

Approval date

2013-12-15, 1392/09/24

Ethics committee reference number

92/130/2123

Health conditions studied

1

Description of health condition studied

Preterm labor

ICD-10 code

o60

ICD-10 code description

Preterm labour and delivery

Primary outcomes

1

Description

Respiratory distress syndrome

Timepoint

After delivery

Method of measurement

sign and symptoms by pediatrician

Secondary outcomes

1

Description

intra ventricular hemorrhage

Timepoint

After birth up to discharge.

Method of measurement

Diagnosis by pediatrician.

2

Description

retinopathy

Timepoint

After birth up to discharge.

Method of measurement

Diagnosis by ophthalmologist

3

Description

necrotizing enter colitis

Timepoint

After birth up to discharge.

Method of measurement

Diagnosis by pediatrician.

4

Description

neonatal death

Timepoint

After birth up to discharge.

Method of measurement

neonatal sheet

5

Description

NICU admission

Timepoint

After birth up to discharge

Method of measurement

neonatal sheet

Intervention groups

1

Description

prescription of two doses of 12 milligram betamethasone with 24 hours interval.

Category

Treatment - Drugs

2

Description

prescription of two doses of 12 milligram betamethasone with 12 hours interval.

Category

Treatment - Drugs

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.

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. Motavallian

Street address

Hemmat High way, Chamran Cross.

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

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Position

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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