

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of antenatal betamethasone on prevention of respiratory distress syndrome among neonates with gestational age of 35-36weeks

Protocol summary

Summary

This study investigated the effect of betamethasone on respiratory distress syndrome among neonates with gestational age of 35-36 weeks. Methods: This study was a double blind randomized controlled trial. Pregnant women who were high risk for preterm labor in 35-36 weeks of gestation were evaluated in Besat hospital of Sanandaj city. The intervention and placebo groups were received intramuscularly betamethasone and normal saline, respectively and they were compared for percent of newborns with respiratory distress syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901193666N1**
Registration date: **2010-05-17, 1389/02/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-17, 1389/02/27

Registrant information

Name

Majid Mansoury

Name of organization / entity

Kurdistan University of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of medical sciences

Expected recruitment start date

2006-01-21, 1384/11/01

Expected recruitment end date

2007-03-19, 1385/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of antenatal betamethasone on prevention of respiratory distress syndrome among neonates with gestational age of 35-36weeks

Public title

Effect of antenatal betamethasone on prevention of respiratory distress syndrome among neonates with gestational age of 35-36weeks

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women who were high risk for preterm labor in 35-36 weeks of gestation. Exclusion criteria: labor after week 37, Hypertension, Diabetes, Drug abuser, Anomaly in newborn, PROM.

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)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kurdistan University of medical sciences

Street address

Kurdistan university of medical sciences, Pasdaran Ave

City

Sanandaj

Postal code

Approval date

2006-12-26, 1385/10/05

Ethics committee reference number

4644پ14پ

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

respiratory distress syndrome

Timepoint

one time

Method of measurement

clinical examination and CT scan

Secondary outcomes

1

Description

Brain hemorrhage

Timepoint

one time

Method of measurement

clinical examination and CT scan

Intervention groups

1

Description

intramuscularly betamethasone

Category

Prevention

2

Description

intramuscularly normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Majid Mansouri

Street address

Keshavarz Ave

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of medical sciences

Full name of responsible person

Dr. Heidary

Street address

Pasdaran Ave

City

Sanandaj

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kurdistan 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