Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Betamethasone effect of pregnancy on neonatal outcomes

Protocol summary

Summary

This double blind randomized trial, investigates the effect of injection of Betamethasone before birth for preventing preterm birth in infants among pregnant women with gestational age of 34-37 weeks in Motahhari hospital in Urmia. 200 pregnant women aged between 18 to 45 years who are of high risk for preterm labor in 34-37 weeks will allocate into 2 groups (Betamethasone and control group) based on blocks randomization method (each group contains 100 participants). They will enter to study the order number on the envelope. Intervention group will receive 2 doses of 24 mg of Betamethasone Within 24 hours. Outcome is respiratory disease (respiratory distress syndrome and transient tachypnea) due to the presence of tachypnea; Granting; chest retraction; flaring, cyanosis; increased oxygen demand; type of delivery; gestational age at birth; birth weight; Apgar score; need for surfactant administration; respiratory support; duration of hospitalization and death will be considered

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050217365N2**
Registration date: **2015-05-05, 1394/02/15**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-05-05, 1394/02/15

Registrant information

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Fatemeh Bahadori
Name of organization / entity
Urmia University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Urmia University of Medical Sciences

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Betamethasone effect of pregnancy on neonatal outcomes

Public title

Evaluation of the administration of betamethasone on late preterm labor and its outcomes.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women who are candidate for delivery in 34-37th week of gestational age based on LMP or Ultrasound before 20 weeks of gestation; The informed consent of the method of treatment. Exclusion criteria: Multiple pregnancies; major congenital malformations; hemorrhagic syndromes active major bleeding; clinical evidence of chorioamnionitis, previous use of corticosteroids; the need for quick termination of pregnancy by the mother or fetus; insulin-dependent diabetes; smoking and drugs by the mother; contraindications of corticosteroids.

Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
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
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia, Urmia university of medical sciences
Street address
Urmia, Urmia university of medical sciences
City
Urmia
Postal code
Approval date
2013-03-05, 1391/12/15
Ethics committee reference number
105

Health conditions studied

1

Description of health condition studied
Neonatal respiratory distress syndrome
ICD-10 code
p22
ICD-10 code description
Hyaline Membrane Disease

2

Description of health condition studied
Preterm Labor
ICD-10 code
060
ICD-10 code description
Onset (Spontaneous) of Labor Before 37 Completed Weeks of Gestation

Primary outcomes

1

Description
Respiratory distress syndrome in the baby after birth
Timepoint
Every half hour until 48 hours after birth
Method of measurement
Questionnaire

2

Description
Apgar score
Timepoint
At Birth
Method of measurement
Questionnaire

3

Description
kind of delivery
Timepoint
At Birth
Method of measurement
Questionnaire

4

Description
The need for hospitalization
Timepoint
After Birth
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Gestational age at birth
Timepoint
After birth
Method of measurement
Questionnaire

2

Description
Infant death
Timepoint
At Birth
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: intramuscular injection of 48 mg of betamethasone solution (4 ampoules 12 mg) divided in two doses within 24 hours. Pharmaceutical Company LLP, Iran registration number 1228030994.
Category
Treatment - Drugs

2

Description
Control group: no injection of betamethasone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahhari Hospital
Full name of responsible person
Fatemeh Bahadori
Street address
kowsar center, motahhari Hospital, Kashani St
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Miss Ghafarzade
Street address
Research ward, Setad , Urmia medical sciences university
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Urmia 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
Urmia university of medical sciences
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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