

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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

Name

Fatemeh Bahadori

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 7077

Email address

fbahadory27@yahoo.com

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

Full name of responsible person

BahadoriFatemeh

Position

Associate professore

Other areas of specialty/work

Street address

Motahhari hospital

City

Urmia

Postal code

Phone

+98 44 3223 7077

Fax

Email

fbahadory27@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Urmia university of medical sciences

Full name of responsible person

Bahadori Fatemeh

Position

Perinatology fellowship

Other areas of specialty/work

Street address

Motahhari hospital

City

Urmia

Postal code

Phone

+98 44 3223 7077

Fax

Email

fbahadory27@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Urmia university of medical sciences

Full name of responsible person

Bahadori Fatemeh

Position

Associate professors

Other areas of specialty/work

Street address

Kowsarcenter, Motahhari h

City

Urmia

Postal code

Phone

+98 44 3223 7077

Fax

Email

fbahadory27@yahoo.com

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