

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Assessment of efficacy of antenatal betamethasone on neonatal respiratory outcome of late preterm delivery (34-37 weeks) in singleton pregnancies

Protocol summary

Study aim

Evaluation of the effect of ante-natal betamethasone on the respiratory outcomes of late preterm labors (weeks 34 to 37)

Design

Women with singleton pregnancy at 34 weeks and 0 days to 36 weeks and 6 days and high probability of preterm labor (in weeks 37-34) will enroll in the study. Exclusion criteria include no exact gestational age, cervix dilatation of 4 cm or more, planned delivery after 36 weeks and 6 days, known congenital malformations, received corticosteroids before week 34 or for other indications, fetal death, major fetal anomaly, non-viable fetus, gestational diabetes, diabetes before pregnancy, maternal contraindications for betamethasone, and chorioamnionitis. Patients were randomly assigned into either group of treatment (intramuscular injection of two 12 mg betamethasone doses apart 24 hours) or in the control group according to the random numbers table. Then the women are routinely taken care of. After birth, neonatal data and respiratory outcomes are recorded, too.

Settings and conduct

Study place: Mahdiah hospital Tehran

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with singleton pregnancy at 34 weeks and 0 days to 36 weeks and 6 days and high probability of preterm labor (in weeks 37-34) will enroll in the study. Exclusion criteria: No exact gestational age, cervix dilatation of 4 cm or more, planned delivery after 36 weeks and 6 days, known congenital malformations, received corticosteroids before week 34 or for other indications, fetal death, major fetal anomaly, non-viable fetus, gestational diabetes, diabetes before pregnancy, maternal contraindications for betamethasone, and chorioamnionitis.

Intervention groups

Treatment group: intramuscular injection of two 12 mg betamethasone doses apart 24 hours Control group: delivery without betamethasone injection

Main outcome variables

Neonatal respiratory outcomes (need for CPAP or nasal cannula with high-current continuous, need for continuous high-pressure oxygen with FiO₂ more than 30%, need for mechanical ventilation, need for ECMO or resuscitation at birth, respiratory distress syndrome, neonatal tachypnea, apnea, bronchopulmonary dysplasia, pneumonia, use of surfactant), the need for care in the NICU, and the duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120918010876N3**

Registration date: **2017-12-16, 1396/09/25**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-03, 1396/10/13**

Update count: **1**

Registration date

2017-12-16, 1396/09/25

Registrant information

Name

Masumeh Mirza Moradi

Name of organization / entity

Prinatology department of Mahdiah hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 6263

Email address

m-bakhtiyari@razi.tums.ac.ir

Recruitment status**Recruitment complete****Funding source**

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of efficacy of antenatal betamethasone on neonatal respiratory outcome of late preterm delivery (34-37 weeks) in singleton pregnancies

Public title

Assessment of efficacy of antenatal betamethasone on neonatal respiratory outcome of late preterm delivery (34-37 weeks)

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Singleton pregnancy Gestational age from 34 weeks and 0 days to 36 weeks and 6 days High probability of preterm labor (in weeks 37-34) due to premature rupture of membranes Preterm labor with intact membranes preterm labor with any indication (including previous cesarean section, intrauterine growth retardation (IUGR), Oligohydramnios, pre-eclampsia, etc.)

Exclusion criteria:

No exact gestational age (unknown first day of last menstrual period (LMP) or no ultrasound dating) Cervix dilatation of 4 cm or more Planned delivery after 36 weeks and 6 days Known congenital malformations Received corticosteroids before week 34 or for other indications Fetal death Major fetal anomaly Non-viable fetus Gestational diabetes Diabetes before pregnancy Maternal contraindications for betamethasone Chorioamnionitis

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **200****Randomization (investigator's opinion)**

Randomized

Randomization description

Simple randomization with random number table

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**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-10-10, 1396/07/18

Ethics committee reference number

IR.sbm.u.msp.rec.1396.458

Health conditions studied**1****Description of health condition studied**

Respiratory distress syndrome of newborn

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes**1****Description**

Neonatal respiratory outcomes

Timepoint

After delivery until patient discharge

Method of measurement

Clinical symptoms & signs

2**Description**

NICU admission

Timepoint

After delivery until patient discharge

Method of measurement

Clinical symptoms & signs

3

Description

Hospitalization duration

Timepoint

Patient discharge time

Method of measurement

Hospitalization duration in day and hour

Secondary outcomes

empty

Intervention groups

1

Description

Treatment group: intramuscular injection of 12 mg betamethasone in two doses between 24 hours

Category

Treatment - Drugs

2

Description

Control group: No Treatment

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Dr. Masoome Mirzamoradi

Street address

Mahdieh Hospital, Shoosh Sq.

City

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Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

mahdiyeh-hospital@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences- Mahdieh Hospital

Full name of responsible person

Dr. Masoome Mirzamoradi

Street address

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Email

mahdiyeh-hospital@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences- Mahdieh Hospital

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences- Mahdieh Hospital

Full name of responsible person

Dr. Masoome Mirzamoradi

Position

Perinatologist

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences-
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Full name of responsible person

Dr. Masoome Mirzamoradi

Position

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Latest degree

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Other areas of specialty/work

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Web page address

Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No need for publishing data file

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences-
Mahdieh Hospital

Full name of responsible person

Dr Fatemeh Hasaninejad

Position