Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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: Mahdieh 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

Prinatalogy department of Mahdieh hospital

Country

Iran (Islamic Republic of)

Phone

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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 firt 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.sbmu.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.
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1185817311
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mahdiyeh-haspital@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences- Mahdieh Hospital
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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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Latest degree
Specialist

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Gynecology and Obstetrics

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Person responsible for updating data

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Shahid Beheshti University of Medical Sciences-Mahdieh Hospital

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Gynecology Resident

Latest degree
Medical doctor

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Gynecology and Obstetrics

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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