

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessment of effect of antenatal betamethasone administration on neonatal respiratory morbidity in early term (37 to 38 weeks and 6 days) elective cesarean section

Protocol summary

Study aim

Evaluation the effect of prenatal betamethasone on neonatal respiratory morbidity in early elective cesarean section (37 to 38 weeks and 6 days)

Design

In this randomized clinical trial, women with singleton pregnancy with elective cesarean section at week 37 to 38 weeks and 6 days will enroll in the study. Exclusion criteria include multiple pregnancies, fetus with major congenital anomalies, fetus with other medical or midwifery conditions that give birth earlier, receive dexamethasone or betamethasone during pregnancy, maternal severe hypertension, maternal history of peptic ulcer, and evidences of intrauterine infection. After selecting patients and obtaining written consent, the patients were randomly assigned to one of the two treatment groups (intramuscular injection of betamethasone before cesarean section) or the control group (routine treatment). Then, women are under routine care, and cesarean delivery is done routinely.

Settings and conduct

Study place: Mahdiah hospital Tehran Study procedure: Randomization of patients to intramuscular injection of betamethasone and control groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: women with singleton pregnancy with elective cesarean section at week 37 to 38 weeks and 6 days will enroll in the study. Exclusion criteria: multiple pregnancies, fetus with major congenital anomalies, fetus with other medical or midwifery conditions that give birth earlier, receive dexamethasone or betamethasone during pregnancy, maternal severe hypertension, maternal history of peptic ulcer, and evidences of intrauterine infection

Intervention groups

Treatment group: intramuscular injection of 12 mg betamethasone in two doses between 24 hours, 48 hours

before cesarean section Control group: cesarean section 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: **IRCT20120918010876N4**

Registration date: **2018-01-11, 1396/10/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-11, 1396/10/21**

Update count: **0**

Registration date

2018-01-11, 1396/10/21

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
2017-07-25, 1396/05/03

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 effect of antenatal betamethasone administration on neonatal respiratory morbidity in early term (37 to 38 weeks and 6 days) elective cesarean section

Public title
Effect of steroid on neonatal respiratory morbidity in elective cesarean section in 37 weeks or later

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
referring women for early or 37 to 38 weeks and 6 days elective cesarean section singleton pregnancy
Exclusion criteria:
multiple pregnancies fetus with major congenital anomalies fetus with other medical or midwifery conditions that give birth earlier receive dexamethasone or betamethasone during pregnancy maternal severe hypertension maternal history of peptic ulcer evidences of intrauterine infection

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **220**

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

Ethic's committee of Shahid Beheshti University of Medical Sciences

Street address

Velenjak St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2017-07-25, 1396/05/03

Ethics committee reference number

IR.sbm.u.msp.rec.1396.275

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 (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)

Timepoint

After cesarean until patient discharge

Method of measurement

Clinical symptoms & signs

2

Description

NICU admission

Timepoint

After cesarean until patient discharge

Method of measurement

Clinical symptoms & signs

3

Description

Hospitalization duration

Timepoint

Patient discharge

Method of measurement

Patient discharge in day and hour

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intramuscular injection of 12 mg betamethasone in two doses between 24 hours, 48 hours before cesarean section

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

Tehran

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

Full name of responsible person

Dr. Ali Ziayee

Street address

Next to Taleghani Hospital, Shahid Arabi St., Yemen St., Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

info@sbmua.ac.ir

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

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

Street address

Mahdieh Hospital, Shoosh Sq.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 6263

Fax

Email

drmoradi000@yahoo.com

Web page address

Person responsible for scientific 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

Street address

Mahdieh Hospital, Shoosh Sq.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 6263

Fax**Email**

drmoradi000@yahoo.com

Web page address**Latest degree**

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Mahdieh Hospital, Shoosh Sq.

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 6263

Fax**Email**

z.joshaghani@hotmail.com

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 publication of data file

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

No - There is not 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 Zahra Joshaghani

Position

Gynecology Resident