Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Effect of Antenatal Steroid before Elective Cesarean Section(C/S) on Prevention of Respiratory Morbidity of Term Neonates.

Protocol summary

Summary

General Purpose: To determine the effect of antenatal steroid before Elective C/S on prevention of respiratory morbidity of term neonates. Study design: Randomized, clinical trial without placebo in two centers. The population of the study are babies born to pregnant women admitted to hospital for elective cesarean section in Yahyanejad and Babol Clinic Hospital due to repetitive C/S , in summer till winter 2015. Inclusion criteria for the mothers; Gestational age ≥39 weeks (based on ultrasound examination) and maternal cesarean section indications only because of repetitive C/S. Exclusion criteria for the mothers; mothers with premature delivery, infection, diabetes, premature rupture of membranes and the use of steroids before birth and also C/s because of other reasons(other than the repeated C/S, such as medical or obstetric underlying disease, for example cephalopelvic disproportion, retinal detachment, and macrosomia. Inclusion criteria for neonates; All infants with gestational age of ≥39 weeks (which is based on ultrasound examination and also by the researcher's physical examination after birth by the New Ballard Scoring system.). Exclusion criteria for neonates; Undelying diseases such as IUGR, macrosomia , perinatal infection, congenital anomalies (Congenital heart diseases, etc.).Mothers are randomly divided into two groups. In this study, for each group of 50 samples were taken. The first groups of mothers' were given Betamethasone (12 mg, daily ,IM, for tow days) within the at least 48 hours before the C/S, but the second groups of mothers' were given nothing ,took only the usual routine care before the C/S. The neonates in both groups after birth were observed for any respiratory problems, including tachypnea, retraction, grunting and cyanosis and also for the requiring any resuscitations immediately after birth. Data like need to be admitted to the neonatal unit, or NICU and doing diagnostic and therapeutic studies were gathered. The incidence of respiratory problems after birth, the diagnosis of the underlying cause of distress, need for hospitalization, length of hospital stay and the need for oxygen administration in the two groups are compared. Data were collected by a questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090923963N1**
Registration date: **2015-11-13, 1394/08/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-11-13, 1394/08/22

Registrant information

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Babol
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Babol university of medical, Street Ganjafrooz, Babol

Expected recruitment start date

2015-08-03, 1394/05/12

Expected recruitment end date

2016-02-01, 1394/11/12

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Antenatal Steroid before Elective Cesarean Section(C/S) on Prevention of Respiratory Morbidity of Term Neonates.

Public title
Effect of Antenatal Steroid before Elective Cesarean Section(C/S) on Prevention of Respiratory Morbidity of Term Neonates.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria for the mothers; gestational age ≥39 weeks (based on ultrasound examination) and maternal cesarean section indications only because of repetitive C/S. Exclusion criteria for the mothers; mothers with premature delivery, infection, diabetes, premature rupture of membranes and the use of steroids before birth and also C/s because of other reasons(other than the repeated C/S, such as medical or obstetric underlying disease, for example cephalopelvic disproportion, retinal detachment, and macrosomia. Inclusion criteria for neonates; All infants with gestational age of ≥39 weeks (which is based on ultrasound examination and also by the researcher's physical examination after birth by the New Ballard Scoring system.). Exclusion criteria for neonates; Underlying diseases such as IUGR, macrosomia , perinatal infection, congenital anomalies (Congenital heart diseases, etc.).
Age
To **50 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Babol University of Medical Sciences Ethics Committee
Street address
Babol University of Medical Sciences Ethics Committee, Ganjafrooz Street, Babol
City
Babol
Postal code
4136747176
Approval date
2015-07-28, 1394/05/06
Ethics committee reference number
5808

Health conditions studied

1

Description of health condition studied
Respiratory distress of newborn
ICD-10 code
P22.0 - P2
ICD-10 code description
Respiratory distress syndrome of newborn- Transient tachypnoea of newborn

Primary outcomes

1

Description
Need for resuscitation, Respiratory distress, Need for oxygen administration, Need to be admitted to the neonatal unit, or NICU and doing diagnostic and therapeutic studies, Need for hospitalization, Length of hospital stay
Timepoint
After birth
Method of measurement
Clinical examination

Secondary outcomes

1

Description
Respiratory distress syndrome and Transient tachypnea of the newborn
Timepoint
After birth
Method of measurement
Clinical examination

Intervention groups

1

Description
Mothers are randomly divided into two groups. In this study, for each group 50 samples were taken. The first groups of mothers' were given Betamethasone(ampoule 4 mg/ml),12 mg, daily, IM, for tow days, within the at least 48 hours before the C/S.

Category
Prevention

2

Description
but the second groups of mothers' were given nothing (Without receiving placebo) ,took only the usual routine care before the C/S. The neonates in both groups after birth were observed for any respiratory problems, including tachypnea, retraction, grunting and cyanosis and also for the requiring any resuscitations immediately after birth. Data like need to be admitted to the neonatal unit, or NICU and doing diagnostic and therapeutic studies were gathered. The incidence of respiratory problems after birth, the diagnosis of the underlying cause of distress, need for hospitalization, length of hospital stay and the need for oxygen administration in the two groups are compared. Data were collected by a questionnaire.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Babol clinic hospital

Full name of responsible person
Dr Mohammad Hossein Kalantar

Street address
Babol clinic hospital, Babol

City
Babol

2

Recruitment center

Name of recruitment center
Yahyanejad hospital

Full name of responsible person
Kalantar Mohammad Hossein

Street address
Yahyanejad Hospital, Street Modarres, Babol

City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Babol University of Medical Sciences

Full name of responsible person
Dr Ali Bijani

Street address
Vice chancellor for research, Babol university of medical, Street Ganjafrooz, Babol

City
Babol

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Babol 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
Babol University of Medical Sciences

Full name of responsible person
Dr Mohammad Hossein Kalantar

Position
Pediatrician

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Other areas of specialty/work
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Person responsible for updating data

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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