

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

Name

Mohammad Hossein Kalantar

Name of organization / entity

Babol

Country

Iran (Islamic Republic of)

Phone

+98 11 3255 2438

Email address

h.kalantar@mubabol.ac.ir

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

Street address

Babol University of Medical Sciences, Street Gangafruz, Babol

City

Babol

Postal code

Phone

+98 11 3255 2438

Fax

Email

kalantar.hossein@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Mousa Ahmadpour-kacho

Position

Associate Professor

Other areas of specialty/work**Street address**

Babol University of Medical Sciences, Street
Gangafrooz, Babol

City

Babol

Postal code**Phone**

+98 11 3219 7667

Fax**Email**

mousa_ahmadpour@hotmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr Mohammad Hossein Kalantar

Position

Periatrician

Other areas of specialty/work**Street address**

Babol University of Medical Sciences, Street
Gangafrooz, Babol

City

Babol

Postal code**Phone**

+98 11 3255 2438

Fax**Email**

kalantar.hossein@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