

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

The effect of antenatal Betamethasone on prevention of neonatal respiratory distress syndrome before elective cesarean section at term

Protocol summary

Study aim

The effect of antenatal Betamethasone on prevention of neonatal respiratory distress syndrome before elective cesarean section at term

Design

Non-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. After selecting patients and obtaining written consent, Patients were randomly assigned into either group of treatment (intramuscular betamethasone or in the control group according to the random numbers table. Then the women are routinely taken care of.

Settings and conduct

Study place: Tbriz Alzahra hospital Study procedure: Accidental division of patients into two groups of 100 patients. Treatment group: intramuscular injection of 12 mg betamethasone in two doses between 24 hours, 48 hours before cesarean section the second groups of mothers' were given nothing (Without receiving placebo) ,took only the usual routine care before the C/S

Participants/Inclusion and exclusion 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 include multiple pregnancies, fetus with major congenital anomalies

Intervention groups

Treatment group: intramuscular injection of 12 mg betamethasone in two doses between 24 hours, 48 hours before cesarean section the second groups of mothers' were given nothing ,took only the usual routine care before the C/S

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: **IRCT20121224011862N3**

Registration date: **2019-06-22, 1398/04/01**

Registration timing: **prospective**

Last update: **2019-06-22, 1398/04/01**

Update count: **0**

Registration date

2019-06-22, 1398/04/01

Registrant information

Name

Farnaz Sahaf

Name of organization / entity

Women's Reproductive Health Research Center

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

sahaf@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-23, 1398/04/02

Expected recruitment end date

2020-07-02, 1399/04/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of antenatal Betamethasone on prevention of neonatal respiratory distress syndrome before elective cesarean section at term

Public title
The effect of antenatal Betamethasone on prevention of neonatal respiratory distress syndrome before elective cesarean section at term

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Women with single pregnancy Gestational age greater than 37 weeks maternal cesarean section indications only because of repetitive C/S.
Exclusion criteria:
 multiple pregnancies fetus with major congenital anomalies Oligohydramnios Polyhydramnios

Age
No age limit

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Not 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
 Ethics Committee Of Tabriz University Of Medical Sciences
Street address
 Third Floor, Central Building of Number2, Golgasht Street
City
 Tabriz

Province
 East Azarbaijan
Postal code
 5166616471
Approval date
 2019-04-22, 1398/02/02
Ethics committee reference number
 IR.TBZMED.REC.1398.071

Health conditions studied

1

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

Primary outcomes

1

Description
 Respiratory distress syndrome in the baby after birth
Timepoint
 Every half hour until 48 hours after birth
Method of measurement
 Physical examination

Secondary outcomes

1

Description
 The need for admission to the neonatal intensive care unit
Timepoint
 From birth to discharge
Method of measurement
 questionnaire

Intervention groups

1

Description
 Intervention group: intramuscular injection of 12 mg betamethasone (manufactured in Iran) in two doses between 24 hours
Category
 Treatment - Drugs

2

Description
 Control group: Group without receive betamethasone
Category
 N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Farnaz Sahaf

Street address

Alzahra Hospital, South Artesh St.

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3553 9161

Email

lahroudin@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

Full name of responsible person

Abolghasem Juiban

Street address

Third Floor, Central Building of Number2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 41 3553 9161

Email

lahroudin@gmail.com

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,Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Farnaz Sahaf

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tabriz University Of Medical Sciences, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Phone

+98 35519161

Email

lahroudin@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Farnaz Sahaf

Position

Associate professor

Latest degree

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Other areas of specialty/work

Gynecology and Obstetrics

Street address

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City

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East Azarbaijan

Postal code

5138665793

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Email

lahroudin@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

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Farnaz Sahaf

Position

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Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

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

Analytic Code

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

Data Dictionary

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