Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Effect of intratracheal budesonide with surfactant in management of respiratory distress syndrome for prevention of bronchopulmonary dysplasia in preterm infants

Protocol summary

Study aim
Determination of efficacy of budesonide with surfactant administration in respiratory distress syndrome for prevention of bronchopulmonary dysplasia

Design
preterm infants that met inclusion criteria, randomly allocated in two groups.In control group, neonates receive initial dose of curosurf 2.5cc/kg intratracheally. Patients in intervention group receive budesonide 0.25 mg/kg in addition to intratracheal curosurf with same initial dose . We follow all neonates till discharge with respect to need for second doses of surfactant at first 3 days of life, reintubation in first 3 days after extubation and duration of supplemental oxygen therapy .

Settings and conduct
Preterm newborn infants who have respiratory distress syndrome will randomly allocate in control group (surfactant) or intervention group (surfactant plus budesonide) by random numbers generated by computerized random number generator in closed envelops. Physician administer the drug in prepared syringes. A nurse who record the patients data will be blind to infant's group. Managing physician is blind about patients groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: preterm infants with gestation age 26-30 weeks and birth weight less than 1250 that have RDS and need to treat with surfactant Exclusion criteria: birth asphyxia, severe congenital anomalies, shock and cardiovascular instability

Intervention groups
In control group, patients receive intratracheal surfactant (Curosurf) with initial dose of 2.5 cc/kg; In intervention group, patients receive budesonide 0.25 mg/kg in addition to surfactant (Curosurf)

Main outcome variables
need to second doses of surfactant at first 3 days of life , need to reintubation in first 3 days after extubation , bronchopulmonary dysplasia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100512003915N20**
Registration date: **2018-07-07, 1397/04/16**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-07, 1397/04/16**
Update count: **0**

Registration date
2018-07-07, 1397/04/16

Registrant information

Name
Manizheh Mostafa Gharehbaghi

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-16, 1397/01/27

Expected recruitment end date
2018-08-22, 1397/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of intratracheal budesonide with surfactant in management of respiratory distress syndrome for prevention of bronchopulmonary dysplasia in preterm infants

Public title
Administration of budesonide with surfactant and prevention of bronchopulmonary dysplasia
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
gestation age 26-30 weeks birth weight less than 1250 grams respiratory distress syndrome
Exclusion criteria:
5 minute Apgar score less than 4 congenital heart disease except patent ductus arteriosus and atrial septal defect necrotizing entrocololitis major congenital anomalies, esophageal atresia, diaphragmatic hernia chromosomal anomalies shock
Age
From **1 day** old to **3 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
newborn infants who met study criteria randomly allocate in two groups (surfactant and surfactant with budesonide) based on generated random number list
Blinding (investigator's opinion)
Double blinded
Blinding description
infants don't know the used drugs. clinical manager administer prepared drug according patients code. outcome is recorded by a nurse who is not aware administered drugs . researcher is blind about patients groups and records data
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences. Gholgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
513866449
Approval date
2018-04-16, 1397/01/27
Ethics committee reference number
IR. TBZMED.REC.1397.041

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
Reintubation in first 3 days after extubation
Timepoint
We evaluate the neonate immediately after intervention and daily till 3 days after intervention and extubation
Method of measurement
tracheal reintubation

2

Description
need to second doses of surfactant
Timepoint
Daily till day 3 of birth and 3 days after intervention
Method of measurement
surfactant administration

3

Description
Bronchopulmonary dysplasia
Timepoint

Daily till 28 days after birth and day 28 after intervention

Method of measurement

need to supplemental oxygen

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: neonates receive budesonide 0.25 mg/kg in addition to intratracheal surfactant

Category

Treatment - Drugs

2

Description

Control group: neonates receive intratracheal surfactant 2.5 cc/kg (crusurf$_9$ Chessia, Italy)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al Zahra Hospital

Full name of responsible person

Dr Manizheh Mostafa Gharehbaghi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Manizheh Mostafa Gharehbaghi

Position

professor

Latest degree

Subspecialist

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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not 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
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