

# 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 envelopes. 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1526 2253

##### Email address

peirovifara@tbzmed.ac.ir

##### 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 enterocolitis 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<sub>9</sub>, 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

##### Street address

South Artesh St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

513866449

##### Phone

+98 41 3553 9161

##### Email

gharehbaghimm@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Barzegar

##### Street address

Gholgasht St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

513866449

##### Phone

+98 41 3335 7310

##### Email

research-vice@tbzmed.ac.ir

#### 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

Pediatrics

##### Street address

South Artesh St.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

513866449

##### Phone

+98 41 3553 9161

##### Email

gharehbaghimm@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Manizheh Gharehbaghi

##### Position

professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

South Artesh St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

513866449

**Phone**

+98 41 3553 9161

**Email**

gharehbaghimm@yahoo.com

**Street address**

South Artesh St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

513866449

**Phone**

+98 41 3553 9161

**Email**

gharehbaghimm@yahoo.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Manizheh Gharehbaghi

**Position**

professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**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