

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the efficacy of HHFNC Versus NCPAP after Surfactant therapy with INSURE method in preterm infants with respiratory distress syndrome

Protocol summary

Summary

This study is conducted to compare the efficacy of high flow nasal cannula and continuous positive airway pressure in surfactant replacement therapy for respiratory distress syndrome. In a randomized clinical trial, 80 preterm infants with gestation age 30-35 weeks and respiratory distress syndrome who admit in NICU for surfactant replacement therapy would be categorized in two groups according to random number list. Infants will be intubate by appropriate size endo- tracheal tube and receive intra tracheal surfactant after confirmation correct position of tracheal tube. Then, infants extubate and randomly allocated in two groups. Patients in group A will receive humidified warm oxygen by high flow nasal cannula and patients in group B support by nasal continuous positive airway pressure. All patients follow and compare for need for re-intubation in next 72 hours after INSURE, pulmonary complications including pneumothorax, chronic lung disease, extra pulmonary complications including retinopathy of prematurity, intra-ventricular hemorrhage, nasal injury and duration of hospitalization.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308283915N9**
Registration date: **2013-09-18, 1392/06/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-18, 1392/06/27

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2013-07-08, 1392/04/17

Expected recruitment end date

2014-03-08, 1392/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of HHFNC Versus NCPAP after Surfactant therapy with INSURE method in preterm infants with respiratory distress syndrome

Public title

comparing two method of respiratory support after surfactant administration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: preterm infants with gestation age

30-35 weeks; admission in NICU with respiratory distress; treatment with surfactant Exclusion criteria: preterm infants with gestation age less than 30 week or above 35 week; intubation immediately after birth before surfactant therapy; respiratory distress score more than 8; severe respiratory distress syndrome in chest x ray.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 80

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**

Ethic Committee of Research Vice Chancellor of Tabriz University of Medical Sciences

Street address

Gholghasht street

City

Tabriz

Postal code**Approval date**

2013-07-07, 1392/04/16

Ethics committee reference number

5/4/3170

Health conditions studied**1****Description of health condition studied**

respiratory distress syndrome

ICD-10 code

p22

ICD-10 code description

Respiratory distress of newborn

Primary outcomes**1****Description**

need for intubation in first 72 hours

Timepoint

every hour till 2 hours

Method of measurement

clinical assessment

Secondary outcomes**1****Description**

bronchopulmonary dysplasia

Timepoint

daily till 28 days

Method of measurement

clinically by supplementary oxygen reception

2**Description**

duration of hospitalization

Timepoint

daily till discharge

Method of measurement

medical records

Intervention groups**1****Description**

Respiratory support by using continuous positive airway pressure (with positive end expiratory pressure 4-6 cm H₂O)) started immediately after surfactant replacement therapy in group B

Category

Treatment - Devices

2**Description**

Respiratory support with humidified high flow nasal cannula (2-6 lit/min) started immediately after surfactant replacement therapy in group A

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Hospital

Full name of responsible person

Manizheh Mostafa Gharehbaghi

Street address

south Artesh street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Vice Chancellor of Tabriz University of
Medical Sciences

Full name of responsible person
Dr Rashidi

Street address
Gholghasht street

City
Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice Chancellor of Tabriz 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
Tabriz University of Medical Sciences

Full name of responsible person
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Position
Associate Professor of pediatrics

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Person responsible for updating data

Contact

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