

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Aug 2026

Comparing two methods of non invasive ventilatory support: nasal contentious positive airway pressure (nCPAP) and nasal intermittent positive pressure ventilation (NIPPV) in preterm infants

Protocol summary

Summary

This is a randomized clinical trial aimed to compare the efficacy of two non invasive ventilatory support in management of respiratory distress syndrome in preterm infants with Respiratory Distress Syndrome. Sixty six preterm infants with birth weight less than 1500 grams randomly allocate in two groups (nasal Continuous Positive Airway Pressure and Nasal Intermittent Positive Pressure Ventilation). We evaluate all infants for need to surfactant replacement therapy, the number of surfactant doses and need for intubation and assisted ventilation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702063915N19**

Registration date: **2017-02-15, 1395/11/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-15, 1395/11/27

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

Research vice chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2017-01-10, 1395/10/21

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing two methods of non invasive ventilatory support: nasal contentious positive airway pressure (nCPAP) and nasal intermittent positive pressure ventilation (NIPPV) in preterm infants

Public title

Comparing two methods of non invasive ventilatory support in preterm infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Preterm infants with gestation ages 28-32 weeks; birth weight less than 2500 grams; diagnosis of Respiratory distress syndrome (based on clinical signs and radiology); need for ventilatory support
Exclusion criteria: Congenital malformations; upper airway anomalies; cardiovascular instability; anemia at birth with hemoglobin less than 10gr/dL; intubation at birth

Age

To **30 days** old

Gender

Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 66

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Tabriz University of Medical Sciences

Street address

Golghasht street

City

Tabriz

Postal code

Approval date

2017-01-09, 1395/10/20

Ethics committee reference number

IR.TBZMED.REC.1395.1048

Health conditions studied

1

Description of health condition studied

Respiratory Distress Syndrome

ICD-10 code

P22

ICD-10 code description

سندرم دیسترس تنفسی

Primary outcomes

1

Description

Need for intubation

Timepoint

First 72 hours of birth

Method of measurement

Intubation based on arterial blood gas analysis

Secondary outcomes

1

Description

Need for Surfactant

Timepoint

First 72 hours of birth

Method of measurement

Surfactant administration via endotracheal tube

Intervention groups

1

Description

Intervention group receive nasal intermittent positive pressure ventilation from first minutes of birth after admission in neonatal intensive care unit

Category

Treatment - Devices

2

Description

Control group receive nasal continuous positive airway pressure from first minutes of birth after admission in neonatal intensive care unit

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU. Alzahra Hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Eivasi. M.D.

Street address

Alzahra Hospital

City

Tabriz

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

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

Ghodratolah Eivasi. M.D.

Position

Subspecialist Assistant

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

Alzahra Hospital

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Postal code**Phone**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Maizheh Mostafa Gharehbaghi.M.D.

Position

Professor

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Web page address**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