

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of prone and supine position on oxygenation of Nasal CPAP treating premature infants with respiratory distress syndrome in Tabriz Alzahra hospital, 2010.

Protocol summary

Summary

The goal of this study is comparison of prone and supine positions on oxygenation of Nasal CPAP treating premature infants. The study population of this study includes 29-34 weeks gestation premature infants, who have respiratory distress syndrome and are under N-CPAP treatment. Participated Infants randomly divided to 2 groups. First group at first placed in supine and then prone position and the second group placed vice versa. Then SatO₂, Fio₂, RR and HR assessed every 10 minutes for totally 30 minutes in each position and documented in questionnaire. After every change position, there were 15 minutes time distance for infant's stabling in new position that is called washout period and after passing this time measure and document of parameters is done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011135168N1**

Registration date: **2011-06-12, 1390/03/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-12, 1390/03/22

Registrant information

Name

Maliheh Assadollahi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy for Research ,Tabriz University of Medical Sciences

Expected recruitment start date

2010-07-01, 1389/04/10

Expected recruitment end date

2010-10-02, 1389/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of prone and supine position on oxygenation of Nasal CPAP treating premature infants with respiratory distress syndrome in Tabriz Alzahra hospital, 2010.

Public title

Effect of supine and prone positions on oxygenation of premature infants with respiratory distress syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 29-34 weeks gestational age, Existence of respiratory distress requires to use of Nasal CPAP, prescribed PEEP amount equal 5 or 6 cmH₂O, The maximum time for receiving CPAP three days, Being NPO, inexistence of congenital heart diseases in infants, inexistence congenital structural defects in respiratory system, not having any physical deformity which be obstacle for change position, 1 passing at least 6 hours

from receiving surfactant, not caring out invasive procedures such as IV line insertion or blood sampling during the parameters measure. Exclusion criteria: Enhancement of respiratory distress and need to intubation, catching pneumothorax and need to chest tube insertion.

Age

From **28 years** old to **34 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Tabriz University of Medical Sciences

Street address

Deputy of Research in Medical Sciences of Tabriz University

City

Tabriz

Postal code

Approval date

2010-09-10, 1389/06/19

Ethics committee reference number

8936

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress of newborn

Primary outcomes

1

Description

arterial oxygen saturation (SatO2)

Timepoint

every 10 minutes and totally 30 minutes in every position

Method of measurement

pulse oximeter and the concentration of received oxygen (FiO2) measured by using oxygen/air Blender

2

Description

heart rate (HR)

Timepoint

every 10 minutes and totally 30 minutes in every position

Method of measurement

pulse oximeter and the concentration of received oxygen (FiO2) measured by using oxygen/air Blender

Secondary outcomes

1

Description

Enhancement of arterial oxygen saturation and reduction of concentration of received oxygen of Nasal CPAP treating premature infant's in Prone position

Timepoint

every 10 minutes and totally 30 minutes in every position

Method of measurement

By using the Masimo Set pulse oximeter structured by SAADAT company and Medin air/oxygen Blender structured by Innovation company

Intervention groups

1

Description

Infant randomly placed in supine or prone position (as first position) and left for 15 minutes to get stable in this situation and no procedure carried out in this period. After 15 minutes arterial oxygen saturation (SatO2) and heart rate (HR) measured by using the pulse oximeter and the concentration of received oxygen (FiO2) measured by using oxygen/air Blender and documented in questionnaire. Then number of infant's respiration (RR) counted by researcher within one minute, and documented in questionnaire

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Alzahra hospital

Full name of responsible person

fatemeh ghorbani

Street address

Alzahra hospital, baghshomal crossroad, Artesh street, Tabriz.

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research in Medical Sciences of Tabriz University

Full name of responsible person

Maliheh Assadollahi

Street address

Pediatric Department of nursing and midwifery faculty

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Deputy of Research in Medical Sciences of Tabriz University

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

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Maliheh Assadollahi

Position

MSc in pediatric Nursing

Other areas of specialty/work

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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