Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of prone and supine position’s effect, on the oxygenation and the vital signs in the preterm neonates who are under the nasal continuous positive air way pressure

Protocol summary

Summary

In a cross over clinical trial ,we investigated effects of different positioning in 30neonates28 to 37 weeks' gestational age who were under mechanical ventilation on nasal continuous positive air way pressure (NCPAP)afterINSURE (i.e. Intubation Surfactant early Extubation)their oxygenation and the vital signs . At first, randomly, they were positioned in supine or prone position for3 houres and then in another position for another 3houres while theiroxygenation , pulse and respiratory rate levels were measured every15minuet and episodes of desaturation, bradycardia ,apnea were measuring for3 houres in one position than 3 houres in another position. Oxygenation index , respiratory and pulse rate and episodes of desaturation, bradycardia and apnea were measuring by continuous monitoring. During the intervention, they received no or minimum procedure. They were excluded if they had the vital sign instability, or continuous episodes of SPO2 les than 80% or apnea, during the study period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109177569N1**
Registration date: **2011-10-28, 1390/08/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-10-28, 1390/08/06

Registrant information

Name

tahereh vafaienejad

Name of organization / entity

Yazd University of Medical Sciences,

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Recruitment status

Recruitment complete

Funding source

Research Deputy for Yazd University of Medical Sciences

Expected recruitment start date

2009-03-08, 1387/12/18

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of prone and supine position’s effect, on the oxygenation and the vital signs in the preterm neonates who are under the nasal continuous positive air way pressure

Public title

The comparison of prone and supine position in preterm neonates under nasal continuous positive air way pressure . in Amiralmomenin hospital in Semnan city

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: infants how, having no contraindicate for prone position Gestational age 28to 37 weeks, under

the nasal continuous positive air way pressure after INSURE from previous 6 hours, having no congenital heart disease, having no intra ventricular hemorrhage, having no congenital diaphragmatic hernia, having no pulmonary interstitial emphysema , having no pneumothorax, having no sepsis with positive culture,Exclusion criteria: vital sign instability or continuous episodes of SPO2 les than 80% or apnea, during the study period.

Age
From **28 years** old to **37 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics in Researches of Medical Sciences 0f Vice Chanceller for Research of yazd University of Medic

Street address
Vice Chanceller for Research, shahid bahonarsquare, University of Medical Sciences,Yazd.

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Postal code
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Approval date
2010-10-27, 1389/08/05

Ethics committee reference number
17/1/81617/پ

Health conditions studied

1

Description of health condition studied
premature newborns under mechanical ventilation

ICD-10 code
P07.3

ICD-10 code description
Disorders related to length of gestation and fetal growth

Primary outcomes

1

Description
Oxygenation,puls rate Respiratory rate

Timepoint
Every15minute for3hr every position

Method of measurement
Monitoring

Secondary outcomes

1

Description
Prevalence of bradycardia,Apnea,decrease of O2SAT,scale FIO2

Timepoint
every position for 3hr

Method of measurement
Monitoring

Intervention groups

1

Description
positioning the newborns in prone position

Category
Treatment - Other

2

Description
positioning the newborns in supine position

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
NICU,Amiralmomenin Hospital

Full name of responsible person
Vafaienejad Tahereh

Street address
Mostafa khomini Ave. Amiralmomenin Hospital Semnan

City
Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Deputy for Research, Yazd University of Medical Sciences

Full name of responsible person
Tahere Salimi

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Vice Chanceller for Research, shahid bahonarsquare, University of Medical Sciences,Yazd.

City
yazd

Grant name

Grant code / Reference number

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

Title of funding source
Deputy for Research, Yazd 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
YazdUniversity of Medical Sciences

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B.S

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