

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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,

Country

Iran (Islamic Republic of)

Phone

+98 35 1824 1751

Email address

vafa.nasim@ssu.ac.ir

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 Of Vice
Chancellor for Research of yazd University of Medic

Street address

Vice Chancellor for Research, shahid bahonar square,
University of Medical Sciences,Yazd.

City

Yazd

Postal code

8916978477

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

Street address

Vice Chancellor for Research, shahid bahonar square, 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**

Yazd University of Medical Sciences

Full name of responsible person

Tahereh Vafaienejad

Position

B.S

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

Mostafa khomini Ave. Amiralmomenin Hospital
semnan

City

Semnan

Postal code

3515644854

Phone

+98 23 1332 6078

Fax

+98 23 1446 1580

Email

vafa_nasim2009@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

Tahereh vafaienejad

Position

B.S

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

Vice Chancellor for Research, shahid bahonar square, University of Medical Sciences, Yazd

City

Yazd

Postal code

3519734731

Phone

+98 23 1332 6078

Fax

+98 23 1446 1580

Email

vafa_nasim2009@yahoo.com

Web page address

vafa_nasim2009@yahoo.com

Person responsible for updating data

Contact**Name of organization / entity**

University of Medical Sciences

Full name of responsible person

Tahereh Vafaienejad

Position

B.S

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

Vice Chancellor for Research, shahid bahonar square, University of Medical Sciences, Yazd

City

Yazd

Postal code

3519734731

Phone

+98 23 1332 6078

Fax

+98 23 1446 1580

Email

vafa@nasim2009@yahoo.com

Web page address

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