

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the Effectiveness of Prone and Supine Position on Arterial oxygen saturation , respiratory rate and heart rate in preterm newborns under nasal continuous positive airway pressure

Protocol summary

Study aim

The aim of this study is to comparison of the effectiveness of supine and prone position on Arterial oxygen saturation , respiratory rate and heart rate in preterm newborns under nasal continuous positive airway pressure

Design

This study was conducted on 62 preterm infants who were under N-CPAP and had inclusion criteria . Neonates were placed in supine position at first for 180 minute and then their position was changed into prone position for another 180 minute . During this period , heart rate, respiratory rate and arterial oxygen saturation were assessed in each neonates every 15 minutes in supine & prone position and were recorded in a questionnaire..

Settings and conduct

This study was conducted on 62 hospitalized preterm infants who were under N-CPAP in the neonatal intensive care unit of Imam Reza Hospital in Kermanshah. . Neonates were placed in supine position at first for 180 minute and then their position was changed into prone position for another 180 minute . During this period , heart rate , respiratory rate and arterial oxygen saturation were assessed in each neonates every 15 minutes in supine & prone position and were recorded in a questionnaire.

Participants/Inclusion and exclusion criteria

The inclusion criteria were : infants with gestational age of 24 to 37 weeks were diagnosed with respiratory distress syndrome under Nasal continuous positive airway pressure .The exclusion criteria were: pulmonary emphysema, pneumothorax, confirmed sepsis with positive culture , congenital heart disease, intraventricular hemorrhage , diaphragmatic hernia.

Intervention groups

62 infants who met the inclusion criteria were placed in supine position at first for 180 minute then their position

was changed into prone position for another 180 minute.During this period , heart rate , respiratory rate and arterial oxygen saturation were assessed every 15 minutes .

Main outcome variables

Heart rate , respiratory rate and arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101018004961N11**

Registration date: **2018-02-16, 1396/11/27**

Registration timing: **retrospective**

Last update: **2018-02-16, 1396/11/27**

Update count: **0**

Registration date

2018-02-16, 1396/11/27

Registrant information

Name

Homa Babaei

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00988314276303 2292 داخلی

Email address

homa_babaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Prone and Supine Position on Arterial oxygen saturation , respiratory rate and heart rate in preterm newborns under nasal continuous positive airway pressure

Public title

Effects of Position on Arterial oxygen saturation , respiratory rate and heart rate in preterm newborns under nasal continuous positive airway pressure

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

neonates with gestational age between 24 to 37 weeks respiratory distress syndrome under Continiuos positive airway pressure through the Nasal CPAP

Exclusion criteria:

congenital heart disease intraventricular hemorrhage diaphragmatic hernia pulmonary emphysema pneumothorax sepsis confirmed by positive culture vital signs instability apnea

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

N/A

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 committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Blvd

City

kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2014-11-11, 1393/08/20

Ethics committee reference number

kums.rec.1394.514

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

Preterm newborn

ICD-10 code

P07.30

ICD-10 code description

Preterm newborn, unspecified weeks of gestation

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

Arterial oxygen saturation

Timepoint

Every 15 minutes and totally 180 minutes in every position

Method of measurement

By pulseoximetry

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

Respiratory rate

Timepoint

Every 15 minutes and totally 180 minute in every position

Method of measurement

By observing the occurrence of breaths

2**Description**

Heart rate

Timepoint

Every 15 minutes and totally 180 minute in every

position
Method of measurement
By pulse oximeter

Intervention groups

1

Description

Intervention group: 62 infants who met the inclusion criteria were placed in supine position at first for 180 minutes and during this period , heart rate , respiratory rate and arterial oxygen saturation were assessed every 15 minutes .

Category

Other

2

Description

Intervention group: 62 infants who met the inclusion criteria were placed in prone position for 180 minutes and during this period , heart rate ,, respiratory rate and arterial oxygen saturation were assessed every 15 minutes .

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Kermanshah University of Medical Sciences

Full name of responsible person

DR Behzad Solimani

Street address

Parastar Boulevard

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drbehzad66@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Farid Najafi

Street address

Deputy of Research, number2 building ,Beheshti Blvd

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fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr Homa Babaei

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr homababaei

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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