

# 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

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##### 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

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6714415333

##### Phone

+98 83 3427 6305

##### Email

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

#### City

kermanshah

#### Province

Kermanshah

#### Postal code

671441533

#### Phone

+98 83 3838 4185

#### Email

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

Pediatrics

##### Street address

Parastar BLVD

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##### Province

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##### Postal code

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##### Email

Homa\_babaei@kums.ac.ir

## Person responsible for scientific 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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## 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**

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**Province**

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**Postal code**

6714415333

**Phone**

+98 83 3427 6305

**Email**

Homa\_babaei@KUMS.AC.IR

## 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