

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

An analysis of the effects of the position of premature infants suffering respiratory distress syndrome on arterial oxygen saturation, vital signs and abdominal distention attached to positive airway pressure device

Protocol summary

Summary

This study aims to assess the impact of the position premature infants with respiratory distress syndrome on arterial oxygen saturation, vital signs and abdominal distention. The population of this study includes 26-week-old to 36-week-old infants, the first and fifth-minute Apgar scoring above seven and those attached to positive airway pressure device. The primary diagnosis of neonates was respiratory distress syndrome and they were dependent of oxygen. Infants requiring intubation were excluded. Samplings were accessibly carried out on 41 infants. Each infant was his/her own control. The position of the first infant, including supine or prone was determined randomly. Subsequently, the change of the positions continued in an alternate fashion to the last infant. The duration of each positioning was 2 hours. The percentage of arterial oxygen saturation, heart rate, respiratory rate and blood pressure in each position was measured every 30 minutes and recorded in questionnaires. The abdominal circumference was measured and recorded before and after each positioning. Body temperature was measured and recorded at the beginning of each position. Following every positioning, there was a 30-minute interval for the infant to reach stability in the new position, titled the washout period, after which parameters were measured and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012101211089N1**

Registration date: **2015-06-13, 1394/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-13, 1394/03/23

Registrant information

Name

Farzaneh Balali

Name of organization / entity

Nursing And Midwifery School Of Shahid Beheshti

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Nursing And Midwifery School of Shahid Beheshti

Expected recruitment start date

2011-11-26, 1390/09/05

Expected recruitment end date

2012-07-20, 1391/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

An analysis of the effects of the position of premature infants suffering respiratory distress syndrome on arterial oxygen saturation, vital signs and abdominal distention attached to positive airway pressure device

Public title

The effect of positions on premature infants with respiratory distress syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 26-36 week-olds (gestational age); early diagnosis of respiratory distress syndrome; without history of congenital diseases; the first and the fifth minute Apgar scoring above seven; attachment to positive airway pressure device (nasal CPAP) Exclusion criteria: Infection; requiring surgery or intubation

Age

From **1 day** old to **2 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **41**

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yaman Street, Shahid Chamran

City

Tehran

Postal code

1985717443

Approval date

2013-06-02, 1392/03/12

Ethics committee reference number

sbmu.rec.1392.141

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome of newborn

ICD-10 code

P22.0

ICD-10 code description

Respiratory distress syndrome of newborn

Primary outcomes

1

Description

Heart rate

Timepoint

Every half hour for 2 hours

Method of measurement

Masimo Set pulse oximeter manufactured by Saadat company

2

Description

Saturation of arterial blood

Timepoint

Every half hour for 2 hours

Method of measurement

Masimo Set pulse oximeter manufactured by Saadat company

3

Description

Abdominal circumference

Timepoint

Every 2 hours, before and after each positioning

Method of measurement

Centimeter

4

Description

Respiratory rate

Timepoint

Every half hour, for 2 hours

Method of measurement

Counted by the researcher

5

Description

Blood pressure

Timepoint

Every half hour, for 2 hours

Method of measurement

Monitoring manufactured by Saadat company

6

Description

Temperature

Timepoint

At the beginning of each position

Method of measurement

Thermometer structured by Welch Allyn

Secondary outcomes

empty

Intervention groups

1

Description

Placing neonate in supine position

Category

Other

2

Description

Placing neonate in prone position

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Alzahra hospital

Full name of responsible person

Mohammad Heidarzaded

Street address

Alzahra hospital, baghshomal crossroad, Artesh street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Nursing And Midwifery School of Shahid Beheshti

Full name of responsible person

Masoumeh Simbar

Street address

Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Yaman Street, Shahid Chamran highway

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Grant name

123802

Grant code / Reference number

10506000

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

Yes

Title of funding source

Vice chancellor for research, Nursing And Midwifery School of Shahid Beheshti

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

Nursing And Midwifery School of Shahid Beheshti

Full name of responsible person

Farzaneh Balali

Position

Graduate Student

Other areas of specialty/work

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Masters

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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