

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effects of prone positions on o2 saturation and heart rate in ventilated premature infants

Protocol summary

Summary

The effects of prone positions on o2 saturation and heart rate in ventilated premature; thirty five cases of low birth weight infants (birth weight less than 2000 g) and premature (less than 34 weeks gestational age) located under mechanical ventilation. Inclusion criteria: infants under mechanical ventilation for 2 hours supine position and physiological parameters recorded during this period every 10 minutes and the infant placed prone position for 2 hours during this time physiological parameters in 10 minutes by monitoring cardiac -inspiratory (monitoring SAADAT) measured by pulse oximeter and recorded and compared with the mean in each state. Infants studied, has the following entry criteria: mechanical ventilated premature newborns; less than 34 weeks of pregnancy; weighing less than 2000 grams; no congenital anomalies; without receipt sedation drugs; without umbilical artery catheters and umbilical vein catheters and chest tubes; at least 4 hours have mechanical ventilation; during the first 4 hours of mechanical ventilation without complications such as pneumothorax . Since to evaluate the arterial blood gas in low birth weight and prematurity is an invasive and painful, and the need for frequent blood sampling, repeated blood sampling decreased blood oxygen saturation is followed by the anemic baby, with comments supervisor, non-invasive monitoring of vital signs was used to evaluate study. The main outcome variable: the condition of the baby in the placement of two supine and prone position, female sex and male sex, gestational age is less than 34weeks gestational age, arterial blood oxygen saturation, birth weight, heart rate.

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-23, 1394/06/01

Registrant information

Name

Tahereh Babuyeh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 9596

Email address

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2014-07-20, 1393/04/29

Expected recruitment end date

2015-04-13, 1394/01/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015032621542N1**

Registration date: **2015-08-23, 1394/06/01**

Scientific title

The effects of prone positions on o2 saturation and heart rate in ventilated premature infants

Public title

The effects of prone positions on o2 saturation and heart

rate in ventilated premature infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: infants mechanical ventilated premature newborns; less than 34 weeks of pregnancy; weighing less than 2000 grams. Exclusion criteria: non mechanical ventilated infants and mechanical ventilated infants over 34 weeks of pregnancy and weight more than 2000 grams; infants with congenital anomalies; under mechanical ventilation for less than 4 hours; recent receive sedation drugs; infants with umbilical vein catheters and umbilical artery catheters and chest tubes; infants during the first 4 hours of mechanical ventilation are complications such as pneumothorax.

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: **35**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganjafrooz st.

City
Babol

Postal code
4775447-976

Approval date
2014-08-02, 1393/05/11

Ethics committee reference number
9328533

Health conditions studied

1

Description of health condition studied
Respiratory and cardiovascular disorders specific to the perinatal period

ICD-10 code
P20-29

ICD-10 code description
Respiratory and cardiovascular disorders specific to the perinatal period

Primary outcomes

1

Description
O2 saturation

Timepoint
Every ten minutes during two hours while studying and sleeping in the supine position the abdomen position

Method of measurement
Pulsoxymeter

2

Description
Heart rate

Timepoint
Every ten minutes during two hours while studying and sleeping in the supine position the abdomen position

Method of measurement
Pulsoxymeter

Secondary outcomes

1

Description
Bradycardia

Timepoint
Every ten minutes during two hours while studying and

Method of measurement
Pulsoxymeter

2

Description
Tachycardia

Timepoint
Every ten minutes during two hours while studying and

Method of measurement
Pulsoxymeter

3

Description
Reduced blood arterial oxygen saturation

Timepoint
Every ten minutes during two hours while studying and Reduced blood arterial oxygen saturation Reduced blood arterial oxygen saturation reduced blood arterial oxygen saturation

Method of measurement

Intervention groups

1

Description

Thirty five cases of low birth weight infants (birth weight less than 2000 g) and premature (less than 34 weeks gestational age) located under mechanical ventilation , Inclusion Entry criteria infants under mechanical ventilation for 2 hours supine position and physiological parameters recorded during this period every 10 minutes and the infant placed prone position for 2 hours During this time physiological parameters in 10 minutes by monitoring cardiac -inspiratory (monitoring SAADAT) measured by pulse oximeter and recorded and compared with the mean in each state

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani Hospital

Full name of responsible person

Tahereh Babuyeh

Street address

Ayatollah Rohani Hospital in Babol

City

Babol

2

Recruitment center

Name of recruitment center

Imam Ayatollah Khomeini

Full name of responsible person

Tahereh Babuyeh

Street address

Imam Ayatollah Khomeini in Sari

City

Sari

3

Recruitment center

Name of recruitment center

Boali Sina hospital

Full name of responsible person

Tahereh Babuyeh

Street address

Boali Sina hospital in Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Akbar Moqhaddamnia

Street address

Babol University of Medical Sciences, Ganjafrooz st.

City

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Tahereh Babuyeh

Position

MSc student of neonatal intensive care nursing

Other areas of specialty/work

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Position

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Babol University of Medical Sciences, Ganjafrooz st.

Full name of responsible person

Tahereh Babuyeh

Position

MSc student of neonatal intensive care nursing

Other areas of specialty/work**Street 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