Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of prone and supine and left lateral position on oxygen saturation and hart rate in very low birth weight

Protocol summary

Summary

The aim of this study is investigation of effect of prone and supine and left lateral Positions on the arterial blood oxygenation and heart rate in very low birth weight neonates .Forty immature infant admitted in NICU of Babol hospitals participant in this study.they were selected randomly after vital sign stability and after 7 days of birth ,with less than 1500 gram weight ,and feeding via OG or breast feeding and without any respiratory problems . Infants were excluded with Congenital anomaly, vascular disease, and pulmonary disease, gasterointestinal and neurological disorders .At first,the infants kept in supine Position for 2 hours, and then change their position to prone , at the end keep their position in left lateral . during this time we recorded all of parameters include arterial blood oxygen, heart rate and patient information on questionnaire every 15 minutes. We calculated mean of each parameters and compare these parameters together about their effect on oxygen saturation and heart rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030421340N1**
Registration date: **2015-06-08, 1394/03/18**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-06-08, 1394/03/18

Registrant information

Name

Samane Mirshahi

Name of organization / entity

Babol University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-09-21, 1394/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of prone and supine and left lateral position on oxygen saturation and hart rate in very low birth weight

Public title

effects of position on oxygen saturation and hart reat in very low birth weight neonate

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age less than 37 weeks and weight less than 1500 gram , infant feeding via OG or breast feeding, and they should not have any respiratory problems. Exclusion criteria: Congenital anomaly, vascular disease, and pulmonary disease, gastrointestinal and neurological disorders, they should not need respiratory support , or having umbilical

catheter or chest tube

Age

From **7 days** old to **29 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ethic committee of Babol University of Medical Sciences

Street address

Ganjafrooz Street

City

babol

Postal code

47754-47976

Approval date

2014-12-16, 1393/09/25

Ethics committee reference number

9339012

Health conditions studied

1

Description of health condition studied

preterm and low birth weight

ICD-10 code

P07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation

Primary outcomes

1

Description

oxygen saturation

Timepoint

every 15 minutes for 2 hours in each position during the study

Method of measurement

oximetric pulse

2

Description

hart reat

Timepoint

every 15 minutes for 2 hours in each position during the study

Method of measurement

monitor

Secondary outcomes

1

Description

decreased oxygen saturation

Timepoint

each position to 2 hours

Method of measurement

each position to 2 hours

2

Description

bradycardia

Timepoint

each position to 2 hours

Method of measurement

each position to 2 hours

Intervention groups

1

Description

positioning the newborns in prone position,positioning the newborns in supine position,positioning the newborns in left latral position

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rohani Hospital

Full name of responsible person

Samane Mirshahi

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University Square, Keshavarz Blvd. Ganjafrooz Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Babol University of Medical Sciences
Full name of responsible person
Dr. Ali Akbar Moghadamnia
Street address
Ganjafrooz Street
City
Babol
Grant name
Grant code / Reference number
9339012
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of 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

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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