

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison between supine and prone positions on the abdominal distention in premature infants supported with nasal positive airway pressure.

Protocol summary

Summary

This is a cross over study which will be done on 35 preterm infants undergoing treatment with nasal positive airway pressure to evaluate the effects of prone and supine positioning on abdominal distention. The setting of this study includes NICUs of Rasule Akram and Akbarabadi hospitals affiliated to Iran University of Medical Sciences. The study population included all the preterm infants admitted in this center. After selecting the samples, the informed consent will be obtained from the parents of the babies. Thus, half of the babies in the study first and then lying prone, supine and the other half of the babies in the supine position and then the abdomen will be a lying position and study results will be compared together. Researcher in order to determine abdominal distention in preterm infants with respiratory distress syndrome under continuous positive airway pressure ventilation will record the pressure on the airways and also amount of received milk in a day. After ensuring of receiving the milk by oral or gavage and after 15 minutes the measurement of waist will start. Also before giving positions to register waist with meter paper that the 1 cm above the navel will be measured, waist to stabilize the situation and the loss due to positions prior to 60 minutes before any positions, with meter Paper will be measured by the researcher. It measures 30, 60, 90, 120 minutes after the position ultimately taken scores of abdominal distention in these two positions, will be compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509211788N11**

Registration date: **2016-01-30, 1394/11/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-30, 1394/11/10

Registrant information

Name

Leili Borimnejad

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6150 4212

Email address

borimnej@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-20, 1394/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between supine and prone positions on the abdominal distention in premature infants supported with nasal positive airway pressure.

Public title

The effects of prone and supine positioning on abdominal

distention.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Infants 32-36 weeks gestational age at birth, birth weight in the range of 1000-2000 g, first and fifth minute Apgar score above 7, the infants who with respiratory distress syndrome that require respiratory assistance, also were not known with revealed congenital disorder and known infection. Infants should be under continuous positive airway pressure ventilation or noninvasive ventilation (Duopap) through the nose with a nasal by prong or mask, under nutrition with breastfeeding or oral gavage. Exclusion criteria: The infants who with congenital malformations like gastroschisis, omphalocele, myelomeningocele, heart abnormalities. if needs to have surgery or mechanical ventilation through an endotracheal tube, detach of continuous positive airway pressure device, re-feeding of infants in less than 120 minutes at the desired positions will be excluded.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 35

Randomization (investigator's opinion)
Randomized

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

Iran University of Medical Sciences

Street address

Office Of Vice Chancellor For International Affairs, Iran
University Of Medical Sciences, Hemmat Highway,
Tehran, Iran.

City

Tehran

Postal code

14665-354

Approval date

2015-08-22, 1394/05/31

Ethics committee reference number

IR.IUMS.REC.1394 9213387202

Health conditions studied

1

Description of health condition studied

Abdominal Distention

ICD-10 code

R14

ICD-10 code description

Symptoms and signs involving the digestive system and abdomen Abdominal Distention

Primary outcomes

1

Description

Abdominal distention

Timepoint

After ensuring of receiving the milk by oral or gavage and after 15 minutes the measurement of abdominal circumference will start. Also before giving positions to register waist with meter paper that the 1 cm above the navel will be measured, waist to stabilize the situation and the loss due to positions prior to 60 minutes before any positions, with meter Paper will be measured by the researcher. It measures 30, 60, 90, 120 minutes after the position ultimately taken scores of abdominal distention in these two positions, will be compared with each other.

Method of measurement

The waist recording will use by the meter paper that be measured 1 cm above the navel.

Secondary outcomes

empty

Intervention groups

1

Description

This cross over study was done on 35 infants who are treated with nasal ventilation positive pressure. After selecting the samples, the informed consent will obtained from the parents of the babies. Thus, half of the babies in the study first and then lying prone, supine and the other half of the babies in the supine position and then the abdomen will be a lying position and results of the study will be compared together. Researcher in order to determine abdominal distention in preterm infants with respiratory distress syndrome under continuous positive airway pressure ventilation will record the pressure on the airways and also amount of received milk in a day. After ensuring of receiving the milk by oral or gavage and after 15 minutes the measurement of abdominal circumference will start. Also before giving

positions to register waist with meter paper that the 1 cm above the navel will be measured, waist to stabilize the situation and the loss due to positions prior to 60 minutes before any positions, with meter Paper will be measured by the researcher. It measures 30, 60, 90, 120 minutes after the position ultimately taken scores of abdominal distention in these two positions, will be compared with each other.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Rasoul Akram Iran University of Medical Sciences and Health

Full name of responsible person

Parisa Mohagheghi

Street address

Tehran, Vali-Asr, Vanak Square, Street Rasheed Yassami

City

Tehran

2

Recruitment center

Name of recruitment center

Akbar-Abadi Hospital affiliated to Iran University of Medical Sciences and Health

Full name of responsible person

Parisa Mohagheghi

Street address

Tehran Street molavi- station Paradise Garden

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

International Campus University of Medical Sciences- Research Center School of Nursing and Midwifer

Full name of responsible person

Lily Borimnejad

Street address

Tehran, Vali-Asr, Vanak Square, Street Rasheed Yassami

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

International Campus University of Medical Sciences-

Research Center School of Nursing and Midwifer

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

School of Nursing and Midwifery, Iran University

Full name of responsible person

Leili Borimnejad

Position

Associate Professor

Other areas of specialty/work

Street address

Tehran, Vali-Asr, Vanak Square, Street Rasheed Yassami

City

Tehran

Postal code

1996713883

Phone

+98 21 8888 2885

Fax

+98 21 8820 1978

Email

Borimnejad.l@iums.ac.ir- fnm@iums.ac.ir

Web page address

http://fnm.iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Parisa Mohagheghi

Position

Associate Professor

Other areas of specialty/work

Street address

Tehran, Rashid yasemi st, Valiasr st

City

Tehran

Postal code

14665-354

Phone

+98 21 86709

Fax

+98 21 8805 2248

Email

drmohagh@yahoo.com

Web page address

WWW.IUMS.AC.IR

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

School of Nursing and Midwifery, Iran University

Full name of responsible person

Fatemeh Pourazar

Position

Graduate student neonatal intensive care

Other areas of specialty/work**Street address**

Tehran, Valiasr st, Rashid yasemi st

City

Tehran

Postal code

14665-354

Phone

+98 21 86709

Fax

+98 21 8805 2248

Email

s_poorazar@yahoo.com

Web page address

http://fnm.iums.ac.ir

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