

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Impact of developmental care on length of stay in infant undergoing mechanical ventilation

Protocol summary

Summary

This is a quasi-experimental study was done to investigate the impact of developmental care on length of mechanical ventilation on 60 inpatient neonates who undergo mechanical ventilation at 4 hospital affiliated to Shahid Beheshti University of Medical Sciences. A convenience sample was selected from 4 hospital in Tehran, Iran that nonrandomly assigned to interventional from Mahdieh Hospital (n=30) and control group (n=30) from other 3 hospital (Mofid Children's Hospital, Imam Hossein Hospital and Shohada Tajrish Hospital). Inclusion criteria: gestational age less than 33 weeks with birth weight equal or less than 2500 g; neonates suffered from respiratory distress syndrome; mechanical ventilation > 24 hours of first 48 hours of life and exclusion criteria: treatment with surfactant, congenital anomalies; asphyxia; respiratory disorders; cyanotic heart disease; mouth and facial abnormalities; maternal use of opium drugs during pregnancy; neonatal death; intraventricular hemorrhage (grade 3 or 4) alongside hydrocephalus; sepsis, necrotizing enterocolitis; growth disorders; bronchopulmonary dysplasia; patent ductus arteriosus requiring treatment; pneumonia caused by mechanical ventilation. Data collection included demographic information that completed under supervision of researchers in the hospitals for intervention groups. Developmental care intervention consist of: change the position every 2-3 hours, hand near face, nesting, Right side or prone position to improve gastric emptying and reduce the effects of gastroesophageal reflux, non-nutritive sucking before invasive intervention and gavage, Using gentle and quiet handling techniques, trunk flexion, shoulder and hip flexion and adduction, prevent suddenly change position and Keep hands of care keeper over the baby's head before beginning any care for providing the infant's sense of care. Care in the intervention group was maintained until the end of the need for mechanical ventilation. Daily nursing care for infants in the control group was conducted.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015070123003N1**

Registration date: **2015-08-09, 1394/05/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-09, 1394/05/18

Registrant information

Name

Sima Sabaghi Faradonbeh

Name of organization / entity

International Branch of Beheshti University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-02-04, 1393/11/15

Expected recruitment end date

2015-06-05, 1394/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of developmental care on length of stay in infant undergoing mechanical ventilation

Public title

Developmental care

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: gestational age less than 33 weeks with birth; weight equal or less than 2500 g; neonates suffered from respiratory distress syndrome; mechanical ventilation > 24 hours of first 48 hours of life. Exclusion criteria: treatment with surfactant; congenital anomalies; asphyxia; respiratory disorders; cyanotic heart disease; mouth and facial abnormalities; maternal use of opium drugs during pregnancy; neonatal death; intraventricular hemorrhage (grade 3 or 4) alongside hydrocephalus; sepsis; necrotizing enterocolitis ; growth disorders; bronchopulmonary dysplasia; patent ductus arteriosus requiring treatment; pneumonia caused by mechanical ventilation.

Age

To 28 days old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not 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

The ethics committee of International Branch of Behesti University of Medical Sciences and Health S

Street address

No.19, Next to Hemat bridge, Street SHahid Abbaspoor, Vali asr(AJ), Tehran

City

Tehran

Postal code

14155-3693

Approval date

2015-02-04, 1393/11/15

Ethics committee reference number

1000/912

Health conditions studied

1

Description of health condition studied

respiratory distress syndrome

ICD-10 code

p 22.0

ICD-10 code description

Hyaline membrane disease

Primary outcomes

1

Description

Developmental care

Timepoint

after intervention

Method of measurement

Data collection included three part demographic questioner. First part, demographic information including weight, sex, age, type of birth, apgar score at the first minute, apgar score at 5 minute that completed under supervision of researchers at the hospitals for intervention groups. Secondary part including developmental care interventions consist of: change the position every 2-3 hours, hand near face, nesting, Right side or prone position to improve gastric emptying and reduce the effects of gastroesophageal reflux, non-nutritive sucking before invasive intervention and gavage, Using gentle and quiet handling techniques, trunk flexion, shoulder and hip flexion and adduction, prevent suddenly change position and Keep hands of care keeper over the baby's head before beginning any care for providing the infant's sense of care and third part including the onset and end time that need for mechanical ventilation.

Secondary outcomes

1

Description

Duration of mechanical ventilation

Timepoint

Since the beginning of mechanical ventilation until maintained until the end of the need for mechanical ventilation.

Method of measurement

Number of days

Intervention groups

1

Description

Researcher in NICU Mahdieh Hospital will present and in relation with the developmental intervention, required explanations will give to nurses. In researcher initially will introduce herself and objectives to the parents of neonates who had inclusion criteria for the study and will sign an informed consent by parents. Then, the first part of a demographic questionnaire will complete by the researcher and the date of onset of mechanical ventilation will record. Developmental care interventions will receive by all neonates who had eligible for inclusion through a trained nurse. Care in the intervention group will maintain until the end of the need for mechanical ventilation.

Category

N/A

2

Description

Inpatient neonates of NICUS Mofid Children's Hospital, Imam Hossein and Shohada Tajrish, Tehran as the control group will receive daily care. Researcher in these hospitals will attend and demographic information questionnaire will fulfill, also the onset and end time that need for mechanical ventilation for 30 cases will record.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Seyyed Abolfazl Afje

Street address

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran

City

Tehran

2

Recruitment center

Name of recruitment center

Mofid Childrens Hospital

Full name of responsible person

Minoo Fallahi

Street address

Shariati Ave, Tehran, Iran

City

Tehran

3

Recruitment center

Name of recruitment center

Imam Hossein Hospital

Full name of responsible person

Ms. Shahrinani

Street address

Madani Ave, Tehran, Iran

City

Tehran

4

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Mahta Fateme Basir

Street address

Tajrish Sq., Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

-

Full name of responsible person

-

Street address

-

City

-

Grant name

Grant code / Reference number

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

Yes

Title of funding source

-

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

International Branch of Beheshti University of Medical Science and Health Services

Full name of responsible person

Sima Sabaghi Faradonbeh

Position

Master student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Science Committee

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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