

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect on the outcome of mechanical ventilation in neonates.

Protocol summary

Summary

This interventional study- outcome based- aimed to assess the impact of nursing care educational program on the outcome of mechanical ventilation in infants undergoing mechanical ventilation in the NICU, and secondary objectives is comparison of the frequency of the most common consequences of mechanical ventilation in neonate, including ventilator-associated respiratory infections, bronchopulmonary dysplasia, pulmonary hemorrhage, retinopathy of prematurity, etc. Research environment is NICU of Comprehensive Women's Hospital (Mirza kouchak Khan) in Tehran. The study population is all infants admitted to the intensive care unit of this hospital and undergoing ventilation from Farvardin 1392 to Farvardin 1393. Inclusions Criteria are admitted discharged or died infants undergoing mechanical ventilation in this interval. All newborns undergoing mechanical ventilation due to asphyxia, congenital anomalies and pulmonary hypoplasia, who have less than 6 hours of mechanical ventilation, and Mid-treated infants who have been separated for any reason from ventilator, have been Excluded. This project is a four-step method. Firstly, to collect demographic information and the consequences caused by the use of mechanical ventilation from infants admitted to the NICU. In the second step (the start of the intervention) guidelines for the care of the infant undergoing ventilation, are provided for NICU nurses. In the third step, Participatory and Questions and Answers training session about care will be held by researchers and professors during specific hours. The final step of the study is conducted, with a time interval of 1 month after completion of the education. In this point, neonatal records infants are investigated to collect information for 6 months. Finally, by comparing the data obtained through statistical tests, results will be announced. The main variables in this study include educational program of nursing care and outcome of mechanical ventilation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013101615040N1**

Registration date: **2014-02-06, 1392/11/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-06, 1392/11/17

Registrant information

Name

Parichehr Talori

Name of organization / entity

School of Nursing and Midwifery, Tehran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect on the outcome of mechanical ventilation in neonates.

Public title

Evaluation of the impact of nursing educational on outcomes among hospitalized neonates under mechanical ventilation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria included infants admitted; discharged ; died in hospital neonatal intensive care unit of a comprehensive women who have been mechanically ventilated. Exclusion criteria included infants who because of asphyxia; congenital malformation complex; hypoplasia of lung, infants less than 6 hours of mechanical ventilation as well as babies in the middle of treatment for any reason be removed from the ventilator

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 120

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**

Ethics Committee of Tehran University of Medical Science

Street address

Tehran University of Medical Sciences, Quds Street, Keshavarz Boulevar

City

Tehran

Postal code**Approval date**

2013-08-21, 1392/05/30

Ethics committee reference number

130/1076 /92/3

Health conditions studied**1****Description of health condition studied**

Broncho pulmonary dysplasia

ICD-10 code

J98.4

ICD-10 code description

lung diseases

2**Description of health condition studied**

Ventilator Associated Pneumonia

ICD-10 code

J69.0

ICD-10 code description

Diseases of the respiratory system

3**Description of health condition studied**

Pulmonary hemorrhage

ICD-10 code

P26.8

ICD-10 code description

Pulmonary hemorrhage

4**Description of health condition studied**

Pneumothorax

ICD-10 code

J98.1

ICD-10 code description

lung diseases

Primary outcomes**1****Description**

Nursing Education Program

Timepoint

After Edite booklet and deliver to ward

Method of measurement

During classes

2**Description**

Outcomes of mechanical ventilation

Timepoint

Before and after training

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Gestational age

Timepoint

Before and after training

Method of measurement

Demographic Information Questionnaire

2

Description

sex

Timepoint

Before and after training

Method of measurement

Demographic Information Questionnaire

3

Description

Birth weight

Timepoint

Before and after training

Method of measurement

Demographic Information Questionnaire

4

Description

Apgar score

Timepoint

Before and after training

Method of measurement

Demographic Information Questionnaire

5

Description

Mothers Diseases

Timepoint

Before and after training

Method of measurement

Demographic Information Questionnaire

6

Description

Type of delivery

Timepoint

Before and after training

Method of measurement

Demographic Information Questionnaire

7

Description

Onset of mechanical ventilation

Timepoint

Before and after training

Method of measurement

Demographic Information Questionnaire

8

Description

Length of stay

Timepoint

Before and after training

Method of measurement

Questionnaire

9

Description

Respiratory problems

Timepoint

Before and after training

Method of measurement

Questionnaire

10

Description

Other respiratory problems

Timepoint

Before and after training

Method of measurement

Questionnaire

Intervention groups

1

Description

Provide guidelines for infant care, including washing hands before and after caring for infants, temperature control, nutrition, respiratory care involves fixing endotracheal tube care, condition, giving good suction, oxygenation, ill deal with infants under ventilator is prepared and placed in the neonatal intensive care unit nurses and multi-session courses in the form of participation and question and answer sessions about where noted.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Women's Hospital

Full name of responsible person

The profiles neonate

Street address

North Nejatollahi Street, Karim Khan Zand Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Jila Mirlashari

Street address

Tehran University of Medical Sciences, Quds Street, Keshavarz Boulevar

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research, Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Parichehr Talori

Position

Neonatal Intensive Care Nursing Graduate Student

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

8 Golestan dormitories, Ahmadi Alley, The Intersection of North Kargar Street, Keshavarz Bolvar, Tehran

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Web page 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