

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect two method care : prone positioning and pron positioning with chest physiotherapy on duration of intubation in premature neonate admitted in NICU in hazrat zainab hospital in shiraz-2015

Protocol summary

Summary

This is a randomized clinical controlled trial. Goal of study: to evaluate the effect of prone positioning and prone positioning with chest physiotherapy on duration of intubation in premature neonate admitted in NICU of Hazrat Zainab hospital. After obtaining informed consent, neonates who meet inclusion criteria, are randomly assigned to three groups (two experimental groups and one control groups), the first experimental group, neonate mechanical ventilation lying prone position. Elbows bent and arms placed at the two sides of the body, while hands were placed at the two sides of head and head was placed towards ventilator tube. For the second group in addition to prone position chest physiotherapy was done every 8 hours. In control group routine care was given. In three groups HR, FIO₂, O₂ SAT, RR, check before and after intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121520316N1**

Registration date: **2015-02-22, 1393/12/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-22, 1393/12/03

Registrant information

Name

Susan Aduband

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect two method care : prone positioning and pron positioning with chest physiotherapy on duration of intubation in premature neonate admitted in NICU in hazrat zainab hospital in shiraz-2015

Public title

Comparison of the effect two method care: prone positioning and pron positioning with chest physiotherapy on duration of intubation in premature neonate

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: gestational age between 26-37 weeks; need to mechanical ventilation in 48 hours after birth; pron position of neonate with confirmation physician; no problem expect respiratory distress syndrome; all of the neonates took surfactant. Exclusion criteria: no cardiac disorder; pulmonary hemorrhage; neuromuscular disease; pneumothorax and death.

Age

From **3 days** old to **3 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

7115

Health conditions studied

1

Description of health condition studied

Respiratory distress syndrome

ICD-10 code

J95-99

ICD-10 code description

Other diseases of respiratory syndrome

Primary outcomes

1

Description

Fio2

Timepoint

Every 1 Hour

Method of measurement

Monitoring and Arterial blood gas

2

Description

Pco2

Timepoint

Twice a day

Method of measurement

Blood gas

3

Description

Heart rate

Timepoint

Every 1 Hour

Method of measurement

Cardiac monitoring

4

Description

Respiratory rate

Timepoint

Twice a day

Method of measurement

Monitoring

5

Description

O2Sat

Timepoint

Every 1 Hour

Method of measurement

Monitoring

Secondary outcomes

1

Description

parameters of mechanical ventilator

Timepoint

two times in day

Method of measurement

monitor of mechanical ventilator

Intervention groups

1

Description

In the control group treat according to routines.

Category

N/A

2

Description

In the experimental group who prone positioning, two small towels were rolled and placed under infants. Knees and abdomen to prevent pressure to knees and chest. In this position, elbows bent and arms placed at the two sides of the body, while hands were placed at the two sides of head and head was placed towards ventilator tube. Fio2, HR, O2sat check every 1 hour.

Category

Prevention

3

Description

In the second experimental group who prone positioning with chest physiotherapy, in addition to, prone position chest physiotherapy was done every 8 hours. Chest physiotherapy includes percussion and vibration. Percussion will be done with face masks, neonate. Vibration will be done with massager of face. HR, FIO2, RR, check every 1 hour.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Zainab Hospital

Full name of responsible person

MS.soltani

Street address

Defa Moghaddas square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Central Building of Shiraz University of Medical Sciences, Zand blvd.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mitra Edraki

Position

MSc of Nursing

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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