

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of facilitated tucking during endotracheal suctioning on pain and coping with stress in preterm infants: a randomized controlled crossover study

Protocol summary

Summary

The aim is to examine the effect of facilitated tucking position during endotracheal suctioning on pain and coping with stress in preterm infants. This is a randomized controlled crossover trial. The population under study includes infants under mechanical ventilation. Sample size is 34 infants. The order of intervention/non-intervention will be randomly determined. Half of the infants receive suctioning without intervention, then suctioning with intervention; and the other half receive suctioning with intervention, then suctioning without intervention. To record data, video recording of the infants is done. Heart rate and oxygen saturation values are recorded from monitors. Main inclusion criteria include age between 29 and 37 weeks gestational age, weight 1200 gram or more, and having endotracheal tube. Main exclusion criteria include having chest tube and receiving opioids or sedatives during past 4 hrs. The intervention is as the following: the infant is placed on one side, the infant's back is gently bended, the legs are got up and flexion at an angle greater than 90 degrees, the shoulders are also constricted up to 90 degrees and the researcher hands are placed over the head close to the mouth or on the infant's face. Main outcomes variables include pain and coping with stress that are measured immediately after suctioning by Preterm Infant Pain Profile and Neonatal Infant Pain Scale, respectively. Coping with stress is time duration required for achieving scores of one or zero based on Neonatal Infant Pain Scale which is measured every 10 seconds.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013062613785N1**

Registration date: **2013-08-02, 1392/05/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-02, 1392/05/11

Registrant information

Name

Hamid Peyrovi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4404

Email address

h-peyrovi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Institutional (Tehran University of Medical Sciences)

Expected recruitment start date

2013-02-08, 1391/11/20

Expected recruitment end date

2013-06-10, 1392/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of facilitated tucking during endotracheal suctioning on pain and coping with stress in preterm

infants: a randomized controlled crossover study

Public title

The effect of facilitated tucking during endotracheal suctioning on pain and coping with stress in preterm infants

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 29 and 37 weeks gestational age Weight 1200 gr and more Having endotracheal tube Exclusion criteria: Any congenital anomaly Having chest tube Any intracranial hemorrhage grade 2 or more Receiving opioids or sedatives during past 4 hrs Convulsion

Age

From **1 year** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

The study is single blind, because the infants do not have knowledge of treatment identification.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Ghods avenue, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2013-01-23, 1391/11/04

Ethics committee reference number

2731/130/91/5

Health conditions studied

1

Description of health condition studied

Respiratory failure

ICD-10 code

J96.9

ICD-10 code description

Respiratory failure, unspecified

Primary outcomes

1

Description

Suctioning associated pain

Timepoint

once, immediately after suctioning

Method of measurement

Preterm Infant Pain Profile (PIPP)

2

Description

Coping with stress

Timepoint

After suctioning, every 10 seconds, until the pain score reaches to 1 or 0 based on Neonatal Infant Pain Scale.

Method of measurement

Neonatal Infant Pain Scale (NIPS)

Secondary outcomes

empty

Intervention groups

1

Description

In cases where the infants is planned to undergo suctioning without intervention, the researcher assistant performs this and the researcher only records the study variables.

Category

Other

2

Description

In cases where the infant is planned to undergo suctioning with intervention, the researcher assistant carries out suctioning and the researcher implements the intervention. To implement facilitated tucking position , the infant is placed on his/her side, his/her back is gently bended, the legs are got up and flexed at an angle greater than 90 degrees, the shoulders are also constricted up to 90 degrees and the researcher hands are placed over the head close to the mouth or on the neonate's face. The interval between suctioning without intervention and suctioning with intervention is at least

two hours.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Hamid Peyrovi

Street address

School of Nursing and Midwifery, Eastern Nosrat,
Tohid Square

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

Akbar Fotouhi

Street address

Department of Epidemiology and Biostatistics, School
of Public Health, Tehran University of Medical
Sciences

City

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

School of Nursing and Midwifery

Full name of responsible person

Hamid Peyrovi

Position

Ph.D/ Faculty member

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Eastern Nosrat,
Tohid Square

City

Tehran

Postal code

1419733171

Phone

+98 21 6105 4404

Fax

+98 66904252

Email

h-peyrovi@tums.ac.ir

Web page address

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

School of Nursing and Midwifery

Full name of responsible person

Hamid Peyrovi

Position

Ph.D in Nursing

Other areas of specialty/work

Street address

School of Nursing and Midwifery, Eastern Nosrat,
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Phone

+98 21 6105 4404

Fax

+98 66904252

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h-peyrvoi@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

School of Nursing and Midwifery

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Hamid Peyrovi

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+98 66904252

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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