

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparing the effect of swaddling and facilitated tucking position on pain intensity and changing in Physiological parameters of premature infants during non-invasive application with NCPAP

Protocol summary

Study aim

Comparing the effect of swaddling and facilitated tucking position on pain intensity and changes in Physiological parameters of premature infants during non-invasive application with NCPAP

Design

Premature infants hospitalized in the cardiac intensive care unit between 28 and 32 weeks were randomly assigned to one of three groups: swaddling, fetal position, and control. In all three groups, variables of pain intensity, heart rate, and percentage of oxygen saturation were measured before the start of the study. Then, after random allocation to the study groups, pain intensity, pulse, and oxygen saturation percentage were measured during nasal tube insertion, after the nasal tube was fixed, and every half hour for up to two hours.

Settings and conduct

Neonatal intensive care unit of Kamali's hospital inN Karaj, Iran

Participants/Inclusion and exclusion criteria

Premature newborns between 28 to 32 weeks of gestational age Inclusion criteria: APGAR score higher than 7; birth weight between 1000 to 2000 gr. Exclusion criteria: Asphyxia during delivery; Addiction in newborn's mother

Intervention groups

Groups of study: 1. Swaddling 2. Facilitated tucking positioning 3. Control group

Main outcome variables

1. Pain intensity due to nasal tube for NCPAP mode 2. Heart rate 3. Spo2 saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101108005134N14**

Registration date: **2023-04-18, 1402/01/29**

Registration timing: **prospective**

Last update: **2023-04-18, 1402/01/29**

Update count: **0**

Registration date

2023-04-18, 1402/01/29

Registrant information

Name

Ali Fakhr-Movahedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4192

Email address

Alimovi49@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-29, 1402/02/09

Expected recruitment end date

2023-08-06, 1402/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of swaddling and facilitated tucking position on pain intensity and changing in Physiological parameters of premature infants during non-invasive

application with NCPAP

Public title

Comparing of swaddling and facilitated tucking positioning on pain intensity of preterm newborns

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

APGAR score higher than 7 Birth weight between 1000 to 2000 gr Newborn's parent consent

Exclusion criteria:

Perinatal asphyxia Congenital anomalies in newborn
Addiction of newborn's mother

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description

After entering the study, infants are divided into swaddle, facilitated tucking position, and control groups based on a 6-block randomized design. The randomization unit is individual. The number of infants in each of the three groups is equal. Randomization will be done by <https://www.sealedenvelope.com>.

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

Ethics committee of Semnan university of medical sciences

Street address

Basij Blvd; The central headquarters of the mobilization of the Boulevard, Semnan University of medical sciences, Vice President for research and technology

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2023-03-13, 1401/12/22

Ethics committee reference number

IR.SEMUMS.REC.1402.001

Health conditions studied

1

Description of health condition studied

Premature neonate

ICD-10 code

P07.3

ICD-10 code description

Preterm [premature] newborn [other]

Primary outcomes

1

Description

Pain intensity

Timepoint

Beginning of the study, during insertion of the nasal tube, after fixation of the nasal tube, every 30 minutes until 2 hours.

Method of measurement

Neonatal Infant Pain Scale

2

Description

Heart rate

Timepoint

Beginning of the study, during insertion of the nasal tube, after fixation of the nasal tube, every 30 minutes until 2 hours.

Method of measurement

Pulse oximeter

3

Description

O2 saturation percent

Timepoint

Beginning of the study, during insertion of the nasal tube, after fixation of the nasal tube, every 30 minutes until 2 hours.

Method of measurement

پالس اکسی متر

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: swaddling, so that the infant is completely wrapped in a thin rectangular blanket. In this case, only the infant's head and neck are out of the swaddle.

Category

Treatment - Other

2

Description

Intervention group: facilitated tucking position, which includes keeping the infant's arms and legs in a flexed position, head and legs gathered towards the abdomen, and in a lateral lying position.

Category

Treatment - Other

3

Description

Control group: routine actions, that infant is receive routine's care

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Dr. Maryam Hashemnejad

Street address

Shohada Sq. Kamali St. Kamali Hospital, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Majid Mirmohammadkhani

Street address

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Ali Fakhr-Movahedi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable