

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of standard positioning effects of standard positioning on Physiological responses and pain in operated infants in NICU of children's Hospital : a crossover clinical trial

Protocol summary

Study aim

The effect of standard positioning on physiological responses and pain of neonates admitted to NICU ward

Design

The alarms monitor the physiological responses 30 minutes, 15 minutes immediately before and immediately after, 15 minutes and 30 minutes later by the CRIES instrument, and again the nurse performs routine care procedures and arranges the baby accordingly. Slowly, as soon as the baby leaves the baby, the researcher will position the IPAT to the baby and maintain the standard position using the rolled towel. 30 minutes, 15 minutes and immediately before and immediately after, 15 minutes and 30 minutes after, the physiological responses were monitored and pain scores were assessed by the CRIES instrument

Settings and conduct

The study units are neonates hospitalized in NICU ward of Tabriz Pediatric Educational Center. The sampling will be done on the infants in the available manner. The statistical population consisted of all neonates over 32 weeks old and admitted to NICU ward of pediatric hospital. The study samples will then be selected by lot. The available samples are simply studied until we reach the desired sample size. Available sampling involves non-random selection of samples based on their availability or easy accessibility.

Participants/Inclusion and exclusion criteria

Ministers over 32 weeks old with no motor restrictive surgery or intubation

Intervention groups

The researcher gives the baby the IPAT position and will maintain the standard position using the rolled towel. 30 minutes, 15 minutes and immediately before and immediately after, 15 minutes and 30 minutes after, the physiological responses were monitored and pain scores were measured by the CRIES instrument.

Main outcome variables

Standard positioning is effective on the physiological responses of neonates admitted to the NICU ward.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191020045168N1**

Registration date: **2019-12-25, 1398/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-25, 1398/10/04**

Update count: **0**

Registration date

2019-12-25, 1398/10/04

Registrant information

Name

Leila Ebrahimpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-05-20, 1399/02/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of standard positioning effects of standard positioning on Physiological responses and pain in operated infants in NICU of children's Hospital : a crossover clinical trial

Public title

Investigation of standard positioning effects of standard positioning on Physiological responses and pain in operated infants in NICU

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Neonates over 32 weeks of surgery and admitted to NICU Pediatric Hospital Neonates extubated after surgery

Exclusion criteria:

Transfer from NICU department to other department before sampling Infant death before completing information Perform restrictive surgeries and neck surgeries Surgical neonates who are intubated after surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **34****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

NO.7.West Isar.Alley Isar 7.

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5451657411

Approval date

2019-12-09, 1398/09/18

Ethics committee reference number

IR.TBZMED.REC.1398.938

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

Investigation of standard positioning effects of standard positioning on Physiological responses and pain in operated infants in NICU

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Physiological responses and pain

Timepoint

30 minutes, 15 minutes and immediately before and immediately after, 15 minutes and 30 minutes later, controls physiological responses and scores with pain using the CRIES tool. The distance between the first and second times is 24 hours in the evening shift. No procedure is performed on the baby within 30 minutes before and after scoring

Method of measurement

CRIES pain tool

Secondary outcomes

empty

Intervention groups**1****Description**

A nurse performs care procedures (baby changing probes, gavages, temperature measurements, etc.) on the baby, arranges the baby according to routine, the researcher 30 minutes, 15 minutes and immediately before and immediately, 15 and 30 minutes. The next minute, the physiological response is monitored and the pain score is assessed by the CRIES tool, and the nurse again carries out routine care procedures and arranges the baby, as soon as the baby leaves the baby, standardizing the position to the baby. The standard position will be maintained using the rolled towel. 30 minutes, 15 minutes and immediately before and immediately after, 15 minutes and 30 minutes after, the

physiological responses were monitored and pain scores were assessed by the CRIES instrument. The distance between the first and second times is 24 hours in the evening shift. No procedures are performed on the baby within 30 minutes before and after scoring. The time of last analgesia and type of medication will be recorded. This study will work with each infant for two days for fixed procedures, fixed hours, and constant shifts to be measured.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Children Medical Research & Training Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Leila Ebrahimpour Anbarloo

Position

Nursing Master of Science Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences

Full name of responsible person

Leila Valizadeh

Position

Ph.D Faculty Member

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments