

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effectiveness of Nesting and Posture on Pain and Physiological Criteria in Post-operative Term Neonates

Protocol summary

Study aim

Determining the effect of nesting and positioning on the amount of pain and physiologic measurements of surgical term neonates.

Design

In this study, 75 neonates who undergo surgery and have the inclusion criteria are randomly divided into two groups: intervention and control group

Settings and conduct

.This study is conducted in Sheikh Hospital on postoperative neonates in order to assess the effect of the nest and lateral position on pain score

Participants/Inclusion and exclusion criteria

Inclusion criteria:37-week-old fetal, severe cardiac and vascular disorders ,Surgery without restraint, Exclusion criteria: newborn of addicted mother,

Intervention groups

Intervention group: After the admission of the newborn in the nest, the neonate is placed in the lateral position. After the intervention, physiological parameters and pain score are measured. The interval of measurement is 15 min and 30 min after the intervention. Then, the measurement of physiological parameters and pain score are done every 6 hours for up to 24 h. There is no intervention in the control group.

Main outcome variables

The pain is measured by physiological indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161219031469N2**

Registration date: **2018-03-12, 1396/12/21**

Registration timing: **retrospective**

Last update: **2018-03-12, 1396/12/21**

Update count: **0**

Registration date

2018-03-12, 1396/12/21

Registrant information

Name

Elahe momenie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3846 4785

Email address

momenie2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Department of Mashhad University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Nesting and Posture on Pain and Physiological Criteria in Post-operative Term Neonates

Public title

The effect of nesting on neonates pain control

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining informed consent from parents in order to participate in the intervention pregnant women with gestational age of 37 weeks Apgar Score 7 and higher The absence of severe cardiac and vascular disorders Surgeries without mobility limitation (Hirschsprung, Imperforated Anus, Types of atresia, Malrotation, Pyloric stenosis, Gastric atresia)

Exclusion criteria:

Parental dissatisfaction to participate in the intervention newborn death Addicted mother

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description

75 admitted infants enter the study. the study population are divided to three groups. Samples are selected by simple random sampling method. In this way, by making a draw, the first group is identified.

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

Faculty of Nursing and Midwifery

Street address

Mashhad faculty of Nursing and Midwifery; ibn-e sina st; Doktora crossing

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2017-02-06, 1395/11/18

Ethics committee reference number

ir.mums.rec.1395.512

2

Ethics committee

Name of ethics committee

Faculty of Nursing and Midwifery

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Razavi Khorasan

Postal code

91778-99191

Approval date

2017-01-25, 1395/11/06

Ethics committee reference number

ir.mums.rec.1395.512

Health conditions studied

1

Description of health condition studied

pain of surgery

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Physiological parameters

Timepoint

At the start of intervention, then up to 24 hours

Method of measurement

Measurement of physiological parameters

2

Description

pain

Timepoint

After the intervention,

Method of measurement

Pain assessment scale nips, cries

Secondary outcomes

1

Description

Oxygen saturation

Timepoint

After intervention

Method of measurement

Monitoring

2

Description

Respiratory

Timepoint

After intervention

Method of measurement

Monitoring

3

Description

Blood pressure

Timepoint

After intervention

Method of measurement

Measuring blood pressure

4

Description

Heart rate

Timepoint

Starting the intervention and up to 24 hours

Method of measurement

Monitoring

Intervention groups

1

Description

First group: First intervention group: The newborn is placed in the nest after the admission. The physiological criteria are measured 8 times for 24 hours.

Category

Prevention

2

Description

The second experimental group: Second intervention group: The newborn is placed in lateral position after admission.

Category

Prevention

3

Description

Control group: There is no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh hospital

Full name of responsible person

Elaheh Momenie

Street address

Mashhad Faculty of nursing and Midwifery,Ibn-e Sina St;Doktora Crossing

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

University of Medical Sciences

Street address

Street University Building Qureshi

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Grant name

Grant code / Reference number

950875

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Momenie elahe

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

DR.T.Sadeghy

Position

Phd in pediatrics

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Momenie Elahe

Position**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

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

Informed Consent Form

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

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

Data Dictionary

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

Title and more details about the data/document

Some of the data can be shared

When the data will become available and for how long

Get started six months after printing results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Data access is allowed

From where data/document is obtainable

momenie-09155025202

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

one week

Comments