Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, Malrotion, 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 andMidwifery

Street address

Mashhad facutlty 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 andMidwifery

Street address

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

City

Mashhad

Province

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 intervation

Method of measurement

Monitoring

2

Description
Respiratory
Timepoint
After intervation
Method of measurement
Monitoring

3

Description
Blood pressure
Timepoint
After intervation
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
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3859 1511
Email
Momenie2@mums.ac.ir

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
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3859 1511
Email
momenie2@mums.ac.ir
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
Nursing and Midwifery
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3846 4785
Fax
Email
Momenie2@mums.ac.ir
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
Street address
Mashhad School of Nursing and Midwifery Ibn Sina St.
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3859 1511
Fax
Email
Momenie2@mums.ac.ir
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
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Mashhad faculty of nursing and midwifery,ebn-sinaSt;Doktora crossing
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3846 4785
Fax
Email
Momenie2@mums.ac.ir
Web page address

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