Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Studying the effectiveness of applying neonatal pain management protocol on nurses' clinical performance

Protocol summary

Study aim
Evaluating the effectiveness of evidence-based protocol on the quality of nurses' pain management practice.

Design
Stepped-wedge Randomized Cluster Trial, with 3 clusters, with blind outcome assessors and 50 observation in each period of time.

Settings and conduct
Overally, three neonatal wards and two neonatal intensive care units from 3 centers (clusters) will enter the study. At first, the nurses' performance in neonatal pain management in all 3 centers will be evaluated (preintervention phase). Then, the first center (cluster) is randomly allocated into the intervention arm and second and third centers will be considered as control groups. After that the second center will get the intervention and the third one considered as the control center. The third center will get the intervention bacause of ethical issues, finally. At the end of each phase the quality of nurses' practice in neonatal pain management and the severity of neonatal pain during the procedures will be assessed by the blind observers.

Participants/Inclusion and exclusion criteria
Employed nurses and admitted neonates in the neonatal wards

Intervention groups
Intervention: implementation of neonatal pain management protocol. Control: routine manner of pain management for hospitalized neonates.

Main outcome variables
Nurses' performance in neonatal pain management; neonatal pain severity during the painful procedures and sustainability of the change in nurses performance in neonatal pain management

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210308050636N1**
Registration date: **2021-06-14, 1400/03/24**
Registration timing: **prospective**

Last update: **2021-06-14, 1400/03/24**
Update count: **0**

Registration date
2021-06-14, 1400/03/24

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-06-21, 1401/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effectiveness of applying neonatal pain management protocol on nurses' clinical performance

Public title

Detrmining the effect of applying pain management protocol on nurses' clinical performance

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Nurses working in the neonatal wards and NICUs of the study hospitals MSc degree or higher in Nursing Admitted Neonates in in the neonatal wards and NICUs of the study hospitals Neonates with gestational age 34 week and more

Exclusion criteria:

Having the position of head nurse in the study wards

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In the study interesed centers (n=3) will be allocated randomly. Since all centers will enter the study in a stepwise manner, we will use the random method to determine the order in which they allocate into the intervention arm. Thus, different modes of centers entrance (six modes: 1-2-3 / 1-3-2 / 2-1-2 / 3-3-3 / 1-1-2- / 3-2-1) will be written on the seprate cards and placed inside the sealed envelope. Then one of the envelopes will be selected randomly (a random number between 1 to 6). All eligible nurses will enter the study.

Blinding (investigator's opinion)

Single blinded

Blinding description

Observing and recording the nurses' performance and neonates'pain severity will be done by evaluators who are not aware of the purpose of the study.

Placebo

Not used

Assignment

Parallel

Other design features

These study is a stepped-wedge randomized cluster trial. The three hospitals will be included in the study in the form of three clusters. First, the clusters enter the basic evaluation stage. After collecting information through observation and a protocol-based checklist, the first cluster is randomly allocated to the intervention arm. The research team will teach the content and the manner of using the protocol (using workshop and installing educational posters in the ward) to all nurses working in the neonatal units of interested center. After completing the training program, the protocol will be implemented in neonatal wards of the center and the head nurses will act as mentors to guide the nurses during the implementation of the protocol. While implementing the protocol in the the first center, two other centers will be considered as control centers. They will continue using the routine manner of pain management for the hospitalized neonates. After two weeks, the data related to the quality of nurses' performance in neonatal pain management and the severity of neonatal procedural pain will be collected simultaneously in all three centers. After accomplishing the data gathering, the intervention will be done for the second center and the third center as a control center, will continue using the routine manner of pain management for the hospitalized neonates. After two weeks, the data related to the quality of nurses' performance and the severity of neonatal procedural pain will be collected simultaneously in all two centers. The third center also get the intervention after the completion of the effectiveness evaluation phase, because of ethical issues. After all, the Primary and secondary outcomes, i.e., nurses' performance in the management of neonatal pain and severity on neonatel pain during painful procedures, will be evaluated using a nurses performance checklist (developed based on the protocol) and Profile-Revised (PIPP-R) Premature Infant Pain for 4 months with 2-month intervals to determine the sustenability of practice change in neonatal pain management.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Research and Technology Deputy, Golestan University of Medical Sciences

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Approval date

2021-05-23, 1400/03/02

Ethics committee reference number

IR.GOUMS.REC.1400.039

Health conditions studied

1

Description of health condition studied

Pain management in neonates

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of nurses’ performance in neonatal pain management
Timepoint
At baseline, 7, 10,18, 26 weeks after start of basic data collection
Method of measurement
The designed checklist based on the neonatal pain management protocol

Secondary outcomes

1

Description
Severity on neonatal pain during painful procedures
Timepoint
At baseline, 7, 10,18, 26 weeks after start of basic data collection
Method of measurement
Profile-Revised (PIPP-R) Premature Infant Pain

2

Description
Nurses' adherence to the use of evidence-based protocol and changes in the neonatal pain management process in the relevant wards
Timepoint
At baseline, 7, 10,18, 26 weeks after start of basic data collection
Method of measurement
The designed checklist based on neonatal pain management protocol

Intervention groups

1

Description
Intervention group: the neonatal pain management protocol includes evidence-based recommendations on pain prevention, assessment, pain relief interventions, and documentation. The assessment step describes diagnosing the cause and severity of neonates’ pain using appropriate tools and interpreting the scores. The pain relief interventions include pharmacological methods such as prescribed drugs (painkillers and EMLA Cream, etc.) and/or non-pharmacological methods such as breast milk, sucrose, non-nutritional sucking, KMC, etc. At first, the above mentioned protocol will be developed based on the John Hopkins Nursing Evidence-Based Practice Model and then, after training the nurses working in interested wards about the content and applying method of the protocol the implementation phase of the protocol as an intervention will begin.
Category
Other

2

Description
Control group: routine care
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
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3

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Sponsors / Funding sources

1

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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
Gorgan 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

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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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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