

# 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

Overall, 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 because 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

##### Name

Razieh Talebi

##### Name of organization / entity

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Iran (Islamic Republic of)

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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

Determining 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 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 interested 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 separate 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**

This 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 neonatal 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 sustainability 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

**City**

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**Province**

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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

Taleghani Children's Hospital

##### Full name of responsible person

Homeira Khoddam

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### 2

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##### Name of recruitment center

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#### Recruitment center

##### Name of recruitment center

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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

#### Contact

**Name of organization / entity**  
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## Person responsible for updating data

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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