

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### The effect of the nurse's compassionate speech on the pain and stress of intravenous catheter insertion in premature neonates

#### Protocol summary

##### Study aim

Determining the effect of the nurse's compassionate speech on the pain and stress of premature neonates caused by intravenous catheter insertion

##### Design

A clinical trial with a control group, with single blinded and non randomized parallel groups on 60 premature neonate.

##### Settings and conduct

Neonatal intensive care unite of Ghaem and Imam Reza Mashhad hospitals. with blinding of outcome assessors and data analysts.

##### Participants/Inclusion and exclusion criteria

Entry requirements for infants: A premature neonates with a gestational age of 28 to 34 weeks , A neonate's weighing at least 1 kg , At least one hour has passed since feeding the neonates , Parents' consent to participate in the research , The neonate should be calm and alert , The neonate should be healthy in terms of hearing with the OEA test. Entry requirements for nurses: Willingness to cooperate in this research , At least 3 years of work experience in the neonatal intensive care unit. Conditions for non-entry of infants: A neonate with a history of surgery , A neonate with an Apgar score of 5 minutes below 6 , neonates with major congenital malformations , neonates requiring CPAP or connected to a tracheal tube , A neonate with an addicted mother , A neonate with a history of taking painkillers and sleeping pills in the last 24 hours. Conditions for non-entry of nurses: Violence and tightness of the vocal cords

##### Intervention groups

In the intervention group, in case of need for venipuncture, in addition to performing routine pain-reducing interventions such as using non-nutritive sucking and a nest, the nurse will talk compassionately with the neonate. In the control group, in case of need for venipuncture routine pain-reducing measures such as using non-nutritive sucking and nests will be performed.

##### Main outcome variables

Neonatal pain , Neonatal stress , The success rate of nurses in venipuncture.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230529058335N1**

Registration date: **2023-07-19, 1402/04/28**

Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**

Update count: **0**

##### Registration date

2023-07-19, 1402/04/28

##### Registrant information

##### Name

Reyhaneh Omidvar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3844 1658

##### Email address

omidvarr4012@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2024-03-20, 1403/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of the nurse's compassionate speech on the pain and stress of intravenous catheter insertion in premature neonates

**Public title**

The effect of the nurse's speech on the pain and stress of neonates

**Purpose**

Education/Guidance

**Inclusion/Exclusion criteria****Inclusion criteria:**

Entry requirements for neonates : Neonats weighing more than 1 kg Premature neonats with a gestational age of 28 to 34 weeks Since feeding the neonate at least one hour has passed The neonat should be calm and alert The neonats 's hearing is healthy with the OAE test The parents of the neonat must consent to participate in the research Entry requirements for nurses : Willingness to cooperate in this research At least 3 years of work experience in the neonatal intensive care unit

**Exclusion criteria:**

Conditions for non-entry of neonates : The Apgar score of the fifth minute of the neonat should be less than 6 have a major congenital anomaly The neonat need CPAP or connected to a tracheal tube have a history of taking analgesic and sedative medicine in the past 24 hours The neonat's mother should be addict Have a history of surgery Conditions for non-entry of nurses : Violence and tightness of the vocal cords

**Age**

From **112 days** old to **136 days** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Not randomized

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

Single blinded

**Blinding description**

Outcome assessors, analysts are blinded. The evaluator, who is made up of professors and experts, only performs the grading by watching the movie without sound, and the data analyzer analyzes only through the given numbers from the scales. it is necessary to mention each neonat's form has a code for the control and intervention group, and only I, who record the procedure, know the classification of the codes.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical Sciences

**Street address**

University Street, Central Building of Mashhad University of Medical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91778-99191

**Approval date**

2023-06-24, 1402/04/03

**Ethics committee reference number**

IR.MUMS.NURSE.REC.1402.046

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

The study is about the pain and stress of premature neonats during intravenous catheter insersion.

**ICD-10 code**

G89.1

**ICD-10 code description**

Acute pain, not elsewhere classified

**Primary outcomes****1****Description**

The amount of pain in neonates of the intervention and control groups will be evaluated.

**Timepoint**

1 minute before the start of the intervention, the first 30 seconds of the start of the intervention, 1 and 5 minutes after the end of the intervention

**Method of measurement**

Registering ,the amount of pain in neonates using the (PIPP) premature infant pain profile

**2****Description**

The amount of stress in neonates of the intervention and control groups will be evaluated.

**Timepoint**

1 minute before the start of the intervention, the first 30 seconds of the start of the intervention, 1 and 5 minutes after the end of the intervention

#### **Method of measurement**

Registering the amount of stress in neonates using the (NISS) newborn infant stress scale

## **Secondary outcomes**

### **1**

#### **Description**

Success rate in venous catheter placement

#### **Timepoint**

After each intervention

#### **Method of measurement**

The number of unsuccessful attempts to insert a venous catheter

## **Intervention groups**

### **1**

#### **Description**

Intervention group: 6 nurses who meet the entry criteria are trained in compassionate talking with neonate. And one day, during a shift, they talk to their neonate for at least 45 minutes alternately while taking care. From the second day onwards, whenever the neonate needs veinpuncture, in addition to the usual pain control measures, the nurse will have a compassionate conversation from 5 minutes before the procedure to the end of the procedure. Examinations are done 1 minute before the intervention and the nurse's speech, 30 seconds after the nurse's speech, 1 and 5 minutes after the procedure is finished. the neonate's stress level with the newborn infant stress scale (NISS) and the neonate's pain level with the premature infant pain profile (PIPP) will be measured.

#### **Category**

Behavior

### **2**

#### **Description**

Control group: For the control group, whenever veinpuncture is needed, the usual pain control measures such as non-nutritive sucking and nesting will be performed. And the examinations are done 1 minute before the start of the intervention, 30 seconds after the insertion of the catheter, 1 and 5 minutes after the procedure is finished. the neonate's stress level with the newborn infant stress scale (NISS) and the neonate's pain level with the premature infant pain profile (PIPP) will be measured.

#### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza hospital

##### **Full name of responsible person**

Reyhaneh Omidvar

##### **Street address**

Ebne sina Street ,Imam reza Square

##### **City**

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##### **Postal code**

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### **2**

#### **Recruitment center**

##### **Name of recruitment center**

Ghaem hospital

##### **Full name of responsible person**

Reyhaneh Omidvar

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Ahmad abad Blv

##### **City**

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## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Mashhad University of Medical Sciences

##### **Full name of responsible person**

Dr Majid Ghayour

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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**  
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**  
Reyhaneh Omidvar

**Position**  
Master Of Nursing Student

**Latest degree**  
Bachelor

**Other areas of specialty/work**  
Nursery

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School of Nursing and Midwifery, Doctora Junction,  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
Naghme Razaghi

**Position**  
Assistant Professor

**Latest degree**  
Ph.D.

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## Person responsible for updating data

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Nursery

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School of Nursing and Midwifery, Doctora Junction,  
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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

Not applicable

### 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

At the end of the work and after printing the article, with permission from the Mashhad Nursing and Midwifery Faculty and the relevant professors, the information will be accessible in the central library of the Mashhad Nursing and Midwifery Faculty in the student thesis.

### When the data will become available and for how

**long**

Access starts 2 months after results are published

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

Researchers with related fields can use the data and results by mentioning the reference.

**From where data/document is obtainable**

Correspondence with project manager Dr. Naghme

Razaghi RazaghiN@mums.ac.ir Postal code:

91778-99191

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

Apply by email

**Comments**