

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 2026

### Evaluation the effect of adjusting environmental stimuli on pain when inserting a central catheter in neonates admitted to the neonatal intensive care unit

#### Protocol summary

##### Study aim

Determining the effect of Decrease environmental stimuli, light and sound, on pain in premature infants when inserting a central venous catheter with peripheral access

##### Design

A clinical trial including the control and intervention groups with parallel, non-blind, non-randomized groups was conducted on 60 infants.

##### Settings and conduct

The researcher will be present in the NICU of Abuzar and Imam Hospitals in Ahvaz from 8:00 a.m. to 19:30 and will choose the infants who are the candidates for inserting the central venous catheter with peripheral access. They are divided into two groups of intervention and control and are investigated. The neonatal pain is measured and recorded in the intervention group by premature infant pain measuring instrument (PIPP) while a central venous catheter is inserted, and an eye shield and an earmuff were used for the infants' eyes and ears to reduce the light and sound. Also, the neonatal pain will be measured by PIPP in the control group without any intervention (reduction of peripheral stimuli) while a central venous catheter is inserted.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. The baby is 37-32 weeks old. 2. Have normal vital signs. Exclusion criteria: Congenital anomalies

##### Intervention groups

The intervention group: in this group, the neonatal pain was investigated in 30 premature infants while a central venous catheter was inserted and the light and sound were reduced by using an eye shield and an earmuff of medicine New Matical brand. The pain was measured using premature infant pain measuring instrument. The control group: in this group, the neonatal pain was measured in 30 premature infants with no changes in

light and sound while a central venous catheter was inserted.

##### Main outcome variables

neonate's pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200114046130N1**

Registration date: **2020-12-09, 1399/09/19**

Registration timing: **retrospective**

Last update: **2020-12-09, 1399/09/19**

Update count: **0**

##### Registration date

2020-12-09, 1399/09/19

##### Registrant information

##### Name

Nargess Ranjbari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3290 4432

##### Email address

nargess.ranjbari@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2020-02-20, 1398/12/01

##### Actual recruitment start date

2019-08-23, 1398/06/01  
**Actual recruitment end date**  
 2020-02-20, 1398/12/01  
**Trial completion date**  
 2020-02-20, 1398/12/01

**Scientific title**  
 Evaluation the effect of adjusting environmental stimuli on pain when inserting a central catheter in neonates admitted to the neonatal intensive care unit

**Public title**  
 The effect of reducing environmental stimuli on infant pain when inserting a central venous catheter

**Purpose**  
 Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 The baby is 37-32 weeks old. He does not have a congenital disease. Have normal vital signs.  
**Exclusion criteria:**  
 Congenital anomalies

**Age**  
 To 28 days old

**Gender**  
 Both

**Phase**  
 N/A

**Groups that have been masked**  
*No information*

**Sample size**  
 Target sample size: 60  
 Actual sample size reached: 60

**Randomization (investigator's opinion)**  
 Not randomized

**Randomization description**

**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

Ethics Committee, Faculty of Pharmacy, Nursing and Midwifery, Shahid Beheshti University of Medical

##### Street address

Niayesh intersection, vali asr Blvd

##### City

Tehran

##### Province

Tehran  
**Postal code**  
 1985717443  
**Approval date**  
 2019-06-19, 1398/03/29  
**Ethics committee reference number**  
 IR.SBMU.PHARMACY.REC.1398.062

## Health conditions studied

### 1

#### Description of health condition studied

pain

#### ICD-10 code

G89.18

#### ICD-10 code description

Other acute postprocedural pain

## Primary outcomes

### 1

#### Description

pain

#### Timepoint

During catheterize of the central venous catheter

#### Method of measurement

premature infant pain profile

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

The intervention group: it includes thirty preterm infants admitted to the NICU of Abuzar and Imam Hospitals in Ahvaz city, they were as the candidates for embedding the central catheter with peripheral vascular access. The light and sound of the unit were reduced by using a medical earmuff of New Mathic brand and an eye sheild. The infant's pain was measured using premature infant pain measuring instrument while the central venous catheter was embedded.

#### Category

N/A

### 2

#### Description

Control group: The amount of pain in the newborn when inserting central venous catheter is measured without reducing the peripheral stimuli of light and sound .

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam KHomeini Ahvaz Hospital

**Full name of responsible person**

Nargess Ranjbari

**Street address**

Imam Khomeini Medical Center of Ahvaz, Azadegan street

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Ahwaz

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Khouzestan

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himam@ajums.ac.ir

### 2

#### Recruitment center

**Name of recruitment center**

Abouzar Hospital Ahwaz

**Full name of responsible person**

Nargess Ranjbari

**Street address**

Abouzar hospital.Parastar avenue.

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

afshin zarghi

**Street address**

5th Floor, Bldg No.2, Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak

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14155-6153

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+98 21 2243 9331

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zarghi@sbmu.ac.ir

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Nargess Ranjbari

**Position**

Master's Student of Neonatal Intensive Care Unit

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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Nurssing and Midwifery University of Shahid Beheshti, Niayesh intersection, Vali asr Blvd,

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## Person responsible for scientific inquiries

#### Contact

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**Other areas of specialty/work**  
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## Person responsible for updating data

**Contact**  
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Shahid Beheshti University of Medical Sciences  
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**Position**  
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**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
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**Street address**  
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1985717443

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Questionnaire information and only part of the main outcome

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

6 months

### To whom data/document is available

Nursing students and nurses

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

Using in research related to knowledge of research subject

### From where data/document is obtainable

Nargess Ranjbari. Nargess.Ranjbari@gmail.com

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

The information will be available ten days after receiving the data email

### Comments