Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 sheild 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

City
Ahwaz

Province
Khouzestan

Postal code
6193673111

Phone
+98 61 3222 2922

Email
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.

City
Ahwaz

Province
Khouzestan

Postal code
6163614175

Phone
+98 61 3444 3051

Email
Aboozar-hos@ajums.ac.ir

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

City
Tehran

Province
Tehran

Postal code
14155-6153

Phone
+98 21 2243 9331

Email
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

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

City
Tehran

Province
Tehran

Postal code
1985717443

Phone
+98 21 8865 5366

Email
Nargess.Ranjbari@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Nargess Ranjbari

Position
Master'Student of Neonatal Intensive Care Unit

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing Midwifery,Intersection of Niayesh.Vally Asr Street.

City

Tehran

Province

Khouzestan

Postal code

6352365640

Phone

88655366

Email

Nargess.Ranjbari@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nargess Ranjbari

Position

MSc NICU Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Intersection of niyayesh ,Valiasr St.

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

Nargess.Ranjbari@gmail.com

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