Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Investigating the effect of non-nutritive feeding and olfactory stimulation with breast milk on pain and behavioral responses caused by PICC implantation in premature infants.

Protocol summary

Study aim
Determining the effect of non-nutritive feeding and olfactory stimulation of breast milk on pain and behavioral responses caused by peripheral central catheter implantation of premature infants hospitalized in the neonatal intensive care unit

Design
Sample selection is done in such a way that all the qualified samples are listed, then each of them is given a number that is set by chance. There was no particular order in writing these numbers. In the following, the necessary number of samples will be randomly selected from among the numbers. In replacing people in the control and intervention groups, the method of randomly transformed blocks is used. In this way, the samples eligible to enter the study are selected and randomly placed in two intervention and control groups

Settings and conduct
NICU research site, Imam Khomeini Hospital, Ahvaz Pain in these babies will be measured in three stages before, during and after the intervention using the PIPP tool. 20 seconds to evaluate behavioral indicators 30 seconds to evaluate physiological indicators

Participants/Inclusion and exclusion criteria
Inclusion criteria: the gestational age is at least 28 weeks and at most 36 weeks and 6 days; birth weight above 1500 grams; mother's willingness to participate in the study; stability of clinical and physiological status. Non-entry criteria: refusal of parents to sign the consent form; use of peripheral IV catheters.

Intervention groups
2 minutes before PICC insertion, a 2 x 2 cm cotton ball containing 2.5 ml of breast milk is placed 3 cm from the baby's nose. . In order to perform non-nutritive sucking, a pacifier suitable for the baby's mouth size is used 5 minutes before PICC insertion. In the control group, pain is measured 2-3 minutes before PICC insertion, during work and 30 seconds after.

Main outcome variables
Reducing pain and modulating behavioral responses

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230724058904N2**
Registration date: **2023-08-08, 1402/05/17**
Registration timing: **prospective**

Last update: **2023-08-08, 1402/05/17**
Update count: **0**

Registration date
2023-08-08, 1402/05/17

Registrant information

Name
sara Faramarzi

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
2023-08-23, 1402/06/01

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of non-nutritive feeding and olfactory stimulation with breast milk on pain and behavioral responses caused by PICC implantation in premature infants.

Public title
Investigating the effect of non-nutritive feeding and olfactory stimulation with breast milk on pain and behavioral responses caused by PICC implantation in premature infants.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Infants admitted to the NICU and requiring intravenous (IV) therapy through a PICC The need for TPN or antibiotic therapy for at least 7 days and infants with 1 poor or difficult venous access Birth weight above 1500 grams Absence of mother's addiction and use of drugs related to epilepsy and neuropsychiatric disorders Mother's desire and consent to participate the baby in the study The stability of the clinical and physiological condition of the baby No mechanical ventilation The absence of central nervous system damage, convulsions and other cases), congenital anomalies, genetic and metabolic disorders based on the patient's file The baby has an order to fix PICC.
Exclusion criteria:
Patients for whom central access has already been fixed Use of peripheral IV catheters and umbilical cord catheters or surgically implanted catheters Significant change in hemodynamic stability and restlessness
Age
From **7 months** old to **9 months** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Sample selection is done in such a way that all eligible samples are listed, then each of them is given a number that is set according to coincidence. There was no particular order in writing these numbers. In the following, the necessary number of samples will be randomly selected from among the numbers. In replacing people in the control and intervention groups, the method of randomly transformed blocks is used. In this way, the samples eligible to enter the study are selected and randomly placed in two intervention and control groups.
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 of Jundi Shapur Ahvaz University of Medical Sciences
Street address
Jundishapur University of Medical Sciences, Esfand St., Golestan Boulevard
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ahvaz
Province
Khouzestan
Postal code
15794- 61357a
Approval date
2023-07-03, 1402/04/12
Ethics committee reference number
IR.AJUMS.REC.1402.211

Health conditions studied

1

Description of health condition studied
Pain in premature babies
ICD-10 code
G89.11
ICD-10 code description
Acute pain due to trauma

2

Description of health condition studied
Premature infants
ICD-10 code
P05.0
ICD-10 code description
Premature infants

Primary outcomes

1

Description
Pain
Timepoint

Before the intervention - during the intervention - and up to 30 seconds after the intervention

Method of measurement

PIPP tool

Secondary outcomes

1

Description

Behavioral responses

Timepoint

Before the intervention - during the intervention - and up to 30 seconds after the intervention

Method of measurement

PIPP tool

Intervention groups

1

Description

Intervention group: After wearing a clean gown, wash your hands and arms completely with antimicrobial cleaning materials for three minutes. Then warm your hands with a warmer to get the right temperature. The researcher must make sure that no painful procedures and other pain relieving interventions have been performed 30 minutes before the PICC insertion and the implementation of interventions to prevent bias in the conclusions. Also, the mother was present at the baby's bedside half an hour before. No nutrition has been done. PICC insertion will be done by one of the trained and experienced and licensed personnel in the department. 2 minutes before PICC insertion, a 2 x 2 cm cotton ball containing 2.5 ml of breast milk is placed 3 cm from the baby's nose. The breast milk used in the intervention group was from their own mother, milked by hand and collected before breakfast to avoid the effect of food consumption on its smell, and then frozen. And it is heated to room temperature before intervention and used. In order to perform non-nutritive sucking, a pacifier suitable for the size of the baby's mouth is used 5 minutes before the insertion of the PICC. It should be noted that premature babies admitted to the special department for babies of Imam Khomeini Hospital are continuously under heart monitoring and pulse oximetry. And with continuous measurement of vital signs and indicators such as breathing rate and breathing depth - breathing sounds and breathing patterns - pulse quality and checking for symptoms of respiratory distress including jumping of nasal fins - retraction and increased breathing rate and also according to the history of the disease And the current condition of the patient can estimate the stability of the clinical and physiological condition. Pain in these babies will be measured in three stages before, during and after the intervention using the PIPP tool. Considering that PIPP evaluates the behavioral and physiological indicators of the baby, therefore, the time required to observe the behavior of the baby is 20 seconds and the behavioral and physiological indicators are considered 30 seconds.

Category

Rehabilitation

2

Description

Control group: The method of doing work in the control group is that 2-3 minutes before PICC insertion, during work and 30 seconds after, pain is measured. Parallel to the intervention group, pain score and physiological and behavioral indicators will be measured in the control group using PIPP.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Neonatal Special Care Department of Imam Khomeini Hospital, Ahvaz

Full name of responsible person

Nahid Naseri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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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
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
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Position
Nursing instructor

Latest degree
Master

Other areas of specialty/work
Medical Education

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Position
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Latest degree
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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

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

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