

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of using octopus crochet doll in reducing pain score after blood sampling in premature infants

Protocol summary

Study aim

Determining the effect of using an octopus doll in reducing pain in premature babies hospitalized in the neonatal intensive care unit (NICU) and using it as a relatively easy and cost-effective method in the NICU

Design

80 infants are randomly entered into the intervention or control groups using the block randomization method. Blocks are determined based on a random allocation list using the site www.sealedenvelope.com. Pain scoring will be done by a trained nurse. After determining the baseline pain score in the first blood sampling, in the subsequent blood samplings, 5 minutes before the intervention, two cc of 50% dextrose is given to the infants. In the intervention group, the octopus doll is given to the infant before and after the blood collection and is placed next to the infant during the procedure.

Settings and conduct

This clinical trial will be conducted on premature babies who were born in BuAli Hospital in Sari and will be admitted to the NICU. Due to the nature of the octopus doll, which is given to the baby at the time of blood sampling, and the pain score is based on the changes in the baby's face, blinding is not applicable in this study.

Participants/Inclusion and exclusion criteria

Premature infants with a gestational age of less than 37 weeks, with a minimum birth weight of 500 grams, who are admitted to the NICU and require at least one blood sampling per day will be included in the study.

Intervention groups

In the intervention group, an octopus doll and feeding with 50% dextrose solution are used during blood sampling with a glucometer from the baby's heel. In the control group, only feeding with 50% dextrose solution is used at the time of blood sampling with a glucometer from the baby's heel.

Main outcome variables

The main outcome of the study is the reduction of the average pain score in both intervention and control

groups at the time of blood sampling.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230926059528N1**

Registration date: **2023-10-12, 1402/07/20**

Registration timing: **prospective**

Last update: **2023-10-12, 1402/07/20**

Update count: **0**

Registration date

2023-10-12, 1402/07/20

Registrant information

Name

Shahrokh Mehrpisheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 2334

Email address

sh.mehrpishe@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	Street address Vice chancellor for Research, Moallem square, Sari
Scientific title The effect of using octopus crochet doll in reducing pain score after blood sampling in premature infants	City Sari
Public title The effect of using octopus crochet doll in reducing blood sampling pain in premature infants	Province Mazandaran
Purpose Supportive	Postal code 4815838477
Inclusion/Exclusion criteria Inclusion criteria: Gestational age less than 37 weeks Admission to the neonatal intensive care unit Minimum birth weight of 500 grams At least need blood sampling once a day Exclusion criteria: Congenital abnormalities such as heart, kidney or blood abnormalities or cancer Performing surgery on the baby The presence of disorders that require treatment with opioids, muscle relaxants, antiepileptic drugs, and analgesics Birth trauma Respiratory distress, pneumoperitoneum, atelectasis	Approval date 2023-09-23, 1402/07/01
Age From 1 day old to 30 days old	Ethics committee reference number IR.MAZUMS.REC.1402.392
Gender Both	Health conditions studied 1 Description of health condition studied Blood sampling pain ICD-10 code G89 ICD-10 code description Pain, not elsewhere classified
Phase 3	Primary outcomes 1 Description The average pain score of in two intervention and control groups Timepoint 10 minutes before blood collection, during blood collection and 10 minutes after blood collection Method of measurement The Premature Infant Pain Profile (PIPP)
Groups that have been masked <i>No information</i>	Secondary outcomes empty
Sample size Target sample size: 80	Intervention groups 1 Description Intervention group: In the intervention group, an octopus doll and feeding with 50% dextrose solution are used during blood sampling with a glucometer from the infant's heel. Category Treatment - Other
Randomization (investigator's opinion) Randomized	2 Description Control group: In the control group, only feeding with 50% dextrose solution is used at the time of blood sampling with a glucometer from the infant's heel. Category N/A
Randomization description Neonates are randomly entered into each of the intervention or control groups using the block randomization method. Blocks are determined based on a random allocation list using www.sealedenvelope.com website (block of 4).	
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 Mazandaran University of Medical Sciences	

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu-Ali Sina Hospital

Full name of responsible person

Dr. Shahrokh Mehrpisheh

Street address

Bu-Ali Sina Hospital, Pasdaran Boulevard, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mazandaran University of Medical Sciences

Street address

Vice chancellor for Research and Technology,
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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

Mazandaran 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

Iran University of Medical Sciences

Full name of responsible person

Hani Rostami Rad

Position

Resident of Pediatrics

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Part of the data is accessible

When the data will become available and for how long

Starting in January 2025

To whom data/document is available

Everybody

Under which criteria data/document could be used

Systematic review articles

From where data/document is obtainable

Contact Dr. Shahrokh Mehrpisheh:
shahrokhmehrpisheh@yahoo.com

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

After contact, information is sent within a few days

Comments