

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effect of earmuffs and eye shields on pain in preterm infants during intravenous blood sampling in the neonatal intensive care unite

Protocol summary

Study aim

To determine the effect of earmuffs and eye shields on pain in preterm infants during intravenous blood sampling in the NICUs.

Design

This study is a Randomised clinical trial with a Factorial design

Settings and conduct

The researcher will present the research environment (Rasool Akram hospitals). The samples will be selected through the sequential method and then the intervention order will be assigned through random assignment. Each newborn will receive one of the interventions during blood sampling in a random order within four days. For newborns with earmuffs or eye shields, earmuffs or eye shields will be applied by the researcher 4 hours before blood sampling. At the time of blood sampling, three people will be present at the site, including a fixed nurse to perform all blood sampling, the researcher to record the oxygen saturation and pulse rate from the monitor, the fixed nurse as a researcher's assistance to complete the pain assessment tool. researcher assistant to fill out the pain scale too.

Participants/Inclusion and exclusion criteria

Babies born to mothers with a history of drug abuse, or treated with antidepressants, have an APGAR below 6 in the 5th minute after birth, have congenital anomalies requiring surgery, grade 2 or higher ventricular hemorrhage will not be included in the study.

Intervention groups

A (without earmuffs and eye shields), B (with earmuffs only), C (with eye shields only), D (with earmuffs and eye shields).

Main outcome variables

Pain response during intravenous blood sampling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160119026104N5**

Registration date: **2019-02-06, 1397/11/17**

Registration timing: **retrospective**

Last update: **2019-02-06, 1397/11/17**

Update count: **0**

Registration date

2019-02-06, 1397/11/17

Registrant information

Name

Mahnaz Shoghi

Name of organization / entity

Iran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4687 1192

Email address

shoghi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-21, 1397/08/30

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

2017-11-08, 1396/08/17

Actual recruitment end date

2018-05-20, 1397/02/30

Trial completion date

empty

Scientific title

Effect of earmuffs and eye shields on pain in preterm infants during intravenous blood sampling in the

neonatal intensive care unite

Public title
The effect of earmuffs and eye shields to pain response

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Birth weight 1000 grams or more Apgar score above 6 at 5th minutes after birth. Not having painful procedures 4 hours before the intervention. Non-administration of sedative and muscle relaxants for the newborn. Clinical stability of the newborn.
Exclusion criteria:
having respiratory assist device. Having chest tube. having Congenital anomalies and metabolic disorders. having intraventricular hemorrhage of grade 2 or more

Age
From **203 days** old to **259 days** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **25**
More than 1 sample in each individual
Number of samples in each individual: **1**
Premature infants (37-39 weeks) admitted to the Neonatal intensive care unit
Actual sample size reached: **25**

Randomization (investigator's opinion)
Randomized

Randomization description
First, we will randomize the allocation of treatments to the letters of the square. then we will design an arrangement of 4 letters in a 4 × 4 square array in such a way that each letter occurs once in each row and once in each column. For the Cyclic method, we will write the letters in the top row in alphabetical order. In the second row, shift the letters one place to the right. will Continue like this for other rows.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of IRAN University of Medical Sciences

Street address
school of Nursing and Midwifery., Shahid yasemi Street., North Kordestan highway., Tehran., Iran

City
Tehran

Province
Tehran

Postal code
۱۹۹۶۷۱۳۸۸۳

Approval date
2017-08-08, 1396/05/17

Ethics committee reference number
IR.IUMS.FMD.REC 1396.9313387001

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Premature infant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain during intravenous blood sampling

Timepoint

Before Intravenous blood sampling; During Intravenous blood sampling; After Intravenous blood sampling.

Method of measurement

Premature Infant Pain Profile Scale

Secondary outcomes

empty

Intervention groups

1

Description

Neonate Blood samples will be taken in 4-days with this sequence: (A: Without eye shields and earmuff, B: With earmuff only, C: With eye Shields only, D : With eye shields and earmuff).

Category

N/A

2

Description

Neonate Blood samples will be taken in 4-days with this sequence: (B: With earmuff only, D: With eye shields and earmuff, A: Without eye shields and earmuff, C: With eye Shields only)

Category

N/A

3

Description

Neonate Blood samples will be taken in 4-days with this sequence: (C: With eye Shields only, A: Without eye shields and earmuff, D: With eye shields and earmuff, B: With earmuff only).

Category

N/A

4

Description

Neonate Blood samples will be taken in 4-days with this sequence: (D: With eye shields and earmuff, C: With eye Shields only, B: With earmuff only, A : A: Without eye shields and earmuff)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram hospital

Full name of responsible person

Mahnaz Shoghi

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school of Nursing and Midwifery.,Shahid yasemi Street., North Kordestan highway., Tehran., Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seid Kazam Malakuti

Street address

School of Nursing and Midwifery, Shahid Yasemi Street., North Kordestan Highway., Tehran., IRAN

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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

Iran 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

Mahnaz Shoghi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

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Name of organization / entity

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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

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After Data coding in order to keep the confidentiality of the participants in the research.

When the data will become available and for how long

The end of sampling till six months after article publishing.

To whom data/document is available

Ethical, Reviewer and Editorial committees, Researchers.

Under which criteria data/document could be used

Systematic review and meta-analysis or secondary analysis citation .

From where data/document is obtainable

Mahnaz Shoghi, Email: shoghi.m@iums.ac.ir

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

After sending a request to academic email, we will send our data files up to one week.

Comments