Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

The Effect of Using Eye Shield and Ear Muffs on the Intensity of pain During Venous Blood sampling in Preterm Neonates

Protocol summary

Study aim
General Objective: Determining the effect of eye shield and ear muffs on pain intensity during venous blood sampling in premature infants

Design
Clinical trial, with control group, double-blind, randomized and random allocation based on a sequence generated by computer software and will be performed by random block method to size 4.

Settings and conduct
Background and setting: Neonatal ward of Ayatollah Rouhani Hospital in Babol Methods: In the intervention groups, the use of eye shield and ear muffs will start 15 minutes before blood sampling and will be maintained during blood sampling. the use of eye shield and ear muffs will continue up to 15 minutes after blood sampling. None of interventions will be used in the control group. pain response based on neonatal infant pain scale(NIPS) score, behavioral and physiological changes (respiratory pattern) of the infant is performed by a assistant researcher. Also, the interpretation of the film will be done by a assistant researcher who does not know about groupings and hypotheses.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Premature infants with a gestational age of 32 to 37 weeks, Physiological stability of cardio respiratory, No congenital or genetic abnormalities, Non use of drugs, antidepressants and anticonvulsants by the mother during pregnancy

Intervention groups
"Intervention group1: Eye shield group: Infants who receive eye shield before injection "Intervention group2: Ear muffs group: infants who have earmuffs before the injection. "Intervention group3: eye shield ear muffs group: Infants who receive both eye shield and earmuffs before injection". "Control group: infants that does not receive any interventions".

Main outcome variables
Intensity of pain during venous blood sampling in premature infants

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200913048704N1**
Registration date: **2020-10-27, 1399/08/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-27, 1399/08/06**
Update count: **0**

Registration date
2020-10-27, 1399/08/06

Registrant information

Name
Ali Zabihi

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
2019-11-24, 1398/09/03

Expected recruitment end date
2020-11-15, 1399/08/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The Effect of Using Eye Shield and Ear Muffs on the Intensity of pain During Venous Blood sampling in Preterm Neonates

Public title
The effect of eye shield and ear muffs on the intensity of venous blood sampling pain in preterm neonates

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Premature infants with a gestational age of 32 to 37 weeks Physiological stability of cardio respiratory (percentage of oxygen saturation above 88%, heart rate between 120 to 160, breath rates between 40 to 60 times per minute No congenital or genetic abnormalities Non use of drugs, antidepressants and anticonvulsants by the mother during pregnancy Not receiving anesthesia and anesthesia drugs Lack of intubation 5 minutes, Apgar score above 7

Exclusion criteria:

Age
From **1 day** old to **28 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **148**

Randomization (investigator's opinion)
Randomized

Randomization description
Infants are randomly assigned to each of the four groups of "eye shield", "ear muffs", "ear muffs eye shield" and also "control group". Random allocation will be based on a sequence generated by computer software (QMinim) using the Block randomization with a block size of 4.

Blinding (investigator's opinion)
Double blinded

Blinding description
Intervention groups are infants on whom blood sampling is performed. Infants are unaware of the effects of eye shields and earplugs and are actually blind to the purpose of the study. The analyzer is not aware of the intervention groups and therefore has no bias in interpreting the data.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
University of Medical Sciences , Ganjafrooz Street , Babol , Mazandaran ,Iran

City
Babol

Province
Mazandaran

Postal code
47176-47745

Approval date
2019-10-22, 1398/07/30

Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.188

Health conditions studied

1

Description of health condition studied
Intensity of pain During Venous Blood sampling in Preterm Neonates

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of pain during venous blood sampling in preterm infants

Timepoint
15 minutes before, during and 15 minutes after blood sampling

Method of measurement
Neonatal Infant Pain Scale (NIPS)

Secondary outcomes

1

Description
Infant heart rate changes 15 minutes before, during and 15 minutes after intravenous sampling

Timepoint
15 minutes before, during and 15 minutes after intravenous sampling

Method of measurement
Cardiorespiratory monitoring device

2

Description
Changes in infant respiration rate 15 minutes before, during and 15 minutes after intravenous sampling
Timepoint
15 minutes before, during and 15 minutes after intravenous sampling
Method of measurement
Cardiorespiratory monitoring device

Intervention groups

1

Description
"Intervention Group1: Eye shield group: Infants who receive eye shield from 15 minutes before injection to 15 minutes after injection"
Category
Prevention

2

Description
Control group: infants that does not receive any interventions
Category
Prevention

3

Description
"Intervention group 2: Ear muffs: Infants who receive ear muffs from 15 minutes before injection to 15 minutes after injection"
Category
Prevention

4

Description
"Intervention group 3: Ear muffs shield group: Infants who receive both eye shield and ear muffs from 15 minutes before injection to 15 minutes after injection"
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Ibrahim Hejazian
Street address
Ayatollah Rouhani Hospital, Next to University of Medical Sciences, Ganjafrooz Street , Babol
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
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rezaghadimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Ali Zabihi
Position
Assistant professor
Latest degree
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Other areas of specialty/work
Nursery

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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
Yes - There is a plan to make this available
Title and more details about the data/document
The data will be provided to the interested parties in an encoded form in Excel format, taking into account ethical considerations.
When the data will become available and for how long
After completing the study
To whom data/document is available
Everyone
Under which criteria data/document could be used
After the publication of the article, all analyzes on the data are allowed by all interested people
From where data/document is obtainable
Correspond Author
What processes are involved for a request to access data/document
By sending an email
Comments