Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of combined non-pharmacological interventions on venous blood sampling pain in preterm infants: a clinical trial study

Protocol summary

Study aim
Effect of combined non-pharmacological interventions in relieving pain caused by venous blood sampling in infants

Design
The clinical trial, with the control group, is 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
En Setting: Neonatal intensive care unit of Ayatollah Rouhani Hospital in Babol Methods: In the intervention groups, the use of sucrose swaddle and nonnutritive sucking will start 2 minutes before blood sampling and will be maintained during blood sampling. the use of sucrose swaddle and nonnutritive sucking will continue up to 2 minutes after blood sampling. Sucrose will be used in the control group.

Participants/Inclusion and exclusion criteria
Premature infants with a gestational age of 32 to 36 weeks and six days, stability of vital signs before sampling, absence of congenital or genetic abnormalities

Intervention groups
Infants are randomly assigned to each of the four groups of sucrose, the group of sucrose and non nutritive sucking, the group of swaddling and sucrose, and the combined group of sucrose, non nutritive sucking and swaddling.

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: **IRCT20200913048704N3**
Registration date: **2023-03-25, 1402/01/05**
Registration timing: **prospective**

Last update: **2023-03-25, 1402/01/05**
Update count: **0**

Registration date
2023-03-25, 1402/01/05

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
2023-04-29, 1402/02/09

Expected recruitment end date
2023-06-30, 1402/04/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of combined non-pharmacological interventions on venous blood sampling pain in preterm infants: a clinical trial study

Public title
The effect of combined non-pharmacological interventions on venous blood sampling pain in preterm

infants: a clinical trial study

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Premature infants with a gestational age of 32 to 36 weeks and six days Stability of vital signs before sampling No congenital or genetic abnormalities Non-use of drugs, antidepressants and anticonvulsants by the mother during pregnancy No surgery and receiving anesthesia and anesthesia drugs Lack of intubation

Exclusion criteria:

Abnormalities in the head and skull such as cleft lip and palate and atrial fibrillation Infants who experience more than grade II intraventricular hemorrhage during the study

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **88**

More than 1 sample in each individual

Number of samples in each individual: **1**

Infant

Randomization (investigator's opinion)

Randomized

Randomization description

After applying the Inclusion and exclusion criteria the method of assigning the subjects will be random allocation by permutation block method. Randomizing is at individual level. The size of the blocks is 4 and in each block, each intervention group will be repeated once. As a result, we will have 24 different blocks, each of which will be numbered from 1 to 24 as desired. Then, using the statistical program code rdunif (n=22, b=24, a=1) in R software version 3.6.1, 22 blocks of 4 will be generated, which will produce a total of 88 sequences (It should be noted that this code generates 22 random numbers from the numbers 1 to 24, which are the number of blocks). Using this randomly generated list, infants will be placed In the sucrose group, sucrose swaddle, sucrose non-nutritive sucking and sucrose swaddle non nutritive sucking group. To hide the random allocation list, a special code will be assigned to each of the intervention groups that only the executor of plan is aware of. These codes are written on a piece of paper and placed in a sealed envelope. A unique code for each patient will be written on this paper as well as its envelope. A foil is also placed inside each envelope so that the envelopes are not legible under light. Each envelope also contains a white paper and a carbon. All envelopes are randomly placed in a larger box and sealed in the box. The main researcher, after reviewing the inclusion criteria and obtaining informed consent, as well as registering the patient's details in a special form, will contact the partner who has a random assignment list (except for the main researcher who is not involved in the patient recruitment and sample entry process) and randomization of that research sample will be done. Also, before opening the envelope, this person should write the name and surname and age of the person on the place marked on the envelope so that the writing falls on the paper inside the envelope.

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 sucrose, swaddle, and nonnutritive sucking and are actually blind to the purpose of the study. The analyzer is unaware of the intervention groups and therefore has no bias in interpreting the data.

Placebo

Not used

Assignment

Parallel

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

Gangafrooz Street

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.MUBABOL.REC.1401.167

Health conditions studied

1

Description of health condition studied

Using non-pharmacological interventions to reduce the pain of newborns

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of pain during venous blood sampling in infants
Timepoint
Before blood collection, during blood collection, 15 minutes after blood collection
Method of measurement
Premature infant pain profile

Secondary outcomes

1

Description
Physiological changes of newborns during and after venous blood sampling
Timepoint
Before the intervention, during the intervention and 15 minutes after the intervention
Method of measurement
Use of cardiorespiratory monitoring device

Intervention groups

1

Description
The first intervention group: Sucrose and non nutritive sucking combined group
Category
Other

2

Description
The second intervention group: the combined group of swaddling and sucrose
Category
Other

3

Description
The third intervention group: combined group of sucrose non nutritive sucking and swaddling
Category
Other

4

Description
Control group: sucrose group
Category
Other

Recruitment centers

1

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

1

Sponsor
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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
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
Associate professor
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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
Anyone
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
People can contact the correspond Author by email to receive the article and data analysis.
What processes are involved for a request to access data/document
By Email: zabihi_alii@yahoo.com
Comments