Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of concurrent use of swaddle and sucrose taste on the Intensity of pain During Venous Blood sampling in Neonate: A clinical trial Study

Protocol summary

Study aim
Determining the effect of concomitant use of sucrose and swaddling during blood sampling on pain intensity in 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
Setting: Neonatal ward of Amirkola Hospital in Babol
Methods: In the intervention groups, the use of sucrose and swaddle will start 2 minutes before blood sampling and will be maintained during blood sampling. the use of sucrose and swaddle will continue up to 2 minutes after blood sampling. None of interventions will be used in the control group.

Participants/Inclusion and exclusion criteria
Term neonates with a gestational age of 37-42 weeks - Stability of vital signs before sampling - No congenital or genetic abnormalities - No use of drugs, antidepressants and anticonvulsants by the mother during pregnancy- No surgery and receiving anesthesia drugs 6- No intubation

Intervention groups
Infants are randomly assigned to each of the four groups of "sucrose", "swaddle", "sucrose swaddle" and also "control group".

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: **IRCT20200913048704N2**
Registration date: **2021-07-13, 1400/04/22**
Registration timing: **prospective**

Last update: **2021-07-13, 1400/04/22**
Update count: **0**

Registration date
2021-07-13, 1400/04/22

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
2021-08-03, 1400/05/12

Expected recruitment end date
2021-09-03, 1400/06/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of concurrent use of swaddle and sucrose taste on the Intensity of pain During Venous Blood sampling in Neonate: A clinical trial Study

Public title

The effect of concurrent use of swaddle and sucrose taste on the Intensity of pain During Venous Blood sampling in Neonate: A clinical trial Study

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Term infants with a gestational age of 42-37 weeks 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: **60**

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=15, b=24, a=1) in R software version 3.6.1, 15 blocks of 4 will be generated, which will produce a total of 60 sequences (It should be noted that this code generates 15 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", "swaddle", "sucrose swaddle", and "control" groups. 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 and swaddle 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

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

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

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2020-08-10, 1399/05/20

Ethics committee reference number

IR.MUBABOL.REC.1399.256

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
2 minutes before, during and 2 minutes after blood sampling
Method of measurement
Neonatal Infant Pain Scale

Secondary outcomes

1

Description
Infant heart rate changes 15 minutes before, during and 15 minutes after intravenous sampling
Timepoint
2 minutes before, during and 2 minutes after intravenous sampling
Method of measurement
Cardiorespiratory monitoring device

Intervention groups

1

Description
Intervention group: Sucrose group: Infants who receive 24%sucrose from 2 minutes before injection to 2 minutes after injection. In this group, the standard 24%sucrose, 0/2 ml / kg is used with a 1 ml syringe without a needle.
Category
Prevention

2

Description
Intervention group: Swaddle group: Infants who are swaddled from 2 minutes before injection to 2 minutes after injection. Infants without clothes and with only one diaper, swaddle on a triangular cloth.
Category
Prevention

3

Description
Intervention group: Swaddle sucrose group: Infants who become both receive sucrose and swaddle from 2 minutes before injection to 2 minutes after injection.
Category
Prevention

4

Description
Control group: Control group: Infants who do not receive any of the interventions.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Amirkola Hospital
Full name of responsible person
Ibrahim Hejazian
Street address
Babol - Shafizadeh Amir Kola Children's Hospital
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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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University of Medical Sciences , Ganjafrooz Street , Babol , Mazandaran ,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
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

Ph.D.

Other areas of specialty/work

Nursery

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Position

Assistant professor

Latest degree

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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