Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jun 2026

Comparison of single or three stage administration of oral sucrose drop 24% on reducing the pain of newborns admitted in the intensive care unit

Protocol summary

Study aim

Comparison of single or multiple phase administration of oral sucrose 24% for pain control in neonatal intensive care unit

Design

The study is a randomized clinical trial. 120 newborns enter randomly in the first or second groups (60 subjects). Randomization is through random numbers table.

Settings and conduct

The study is conducted at Bu-Ali Sina hospital in Sari. The film is taken from the 30 seconds before the drug use until 60 seconds after it is consumed (except for the duration of the drug administration). The nurse is aware of the drug usage method. These videos are carefully evaluated by a neonatal specialist who is not aware of the intervention. Also, the results analyzer is not aware of the intervention done in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: neonates in intensive care unit who need heel lance. The exclusion criteria: carbohydrate intolerance due to short gut syndrome ,metabolic or endocrine dysfunction (such as fructose or sucrose intolerance, diabetes), inability to tolerate oral administration of the solution to the tongue, absent/deficient protective airway reflexes, central nervous system dysfunction, use of sedation/analgesics, neuromuscular blocking agents, or anesthetic agents, patient with suspected or confirmed necrotizing enterocolitis, oral surgery, patients on a ketogenic diet, no feeding per oral and neonates with maternal anomaly in their faces

Intervention groups

In this study, neonates receive oral sucrose 24% solution based on their weight, 0.3 mL/kg, either as a single dose 120 seconds (intervention group 1) or in three divided doses 120, 90 and 60 seconds (intervention group 2) before heel lance.

Main outcome variables

Pain score based on Premature Infant Pain Profile Revised (PIPP-R) criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090813002342N8**
Registration date: **2018-09-12, 1397/06/21**
Registration timing: **retrospective**

Last update: **2018-09-12, 1397/06/21**
Update count: **0**

Registration date

2018-09-12, 1397/06/21

Registrant information

Name

Mohammad Reza Rafati

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-01-30, 1395/11/11

Expected recruitment end date

2018-09-17, 1397/06/26

Actual recruitment start date

2017-01-30, 1395/11/11

Actual recruitment end date

2017-09-17, 1396/06/26

Trial completion date

2017-11-21, 1396/08/30

Scientific title

Comparison of single or three stage administration of oral sucrose drop 24% on reducing the pain of newborns admitted in the intensive care unit

Public title

Comparison of single or multiple phase administration of oral sucrose 24%

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1 to 28 day neonates who need blood sampling

Exclusion criteria:

Weight<800 g Neonates with mechanical ventilation Neonates with necrotizing entrocolitis Neonates born from mothers with uncontrolled diabetic Neonates born with congenital anomaly in face No feeding by mouth Neonate with unstable hemodynamic condition Neonate receives antiepleptics, opiates or sedative drugs

Age

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

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Actual sample size reached: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization. Patients based on random numbers table will enter to first or second groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The nurse is aware of drug administration method and at the time of drug taking, the film is not taken. The film is taken from the 30 seconds before the drug is started up to 60 seconds after it is consumed (except for the duration of the druguse) to assess the pain. These videos are carefully evaluated by a neonatologist who is not aware of the intervention done in each group. Statistical analyzer is also not aware of the intervention done in each group.

Placebo

Not used

Assignment

Other

Other design features

Effect of sucrose permanent taste is investigated

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committe of Mazandaran University of Medical Sciences

Street address

Moallem square, Moallem street, Sari

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2017-01-21, 1395/11/02

Ethics committee reference number

IR.MAZUMS.REC.13952433

Health conditions studied

1

Description of health condition studied

Pain in critically ill neonates hospitalized at intensive care unit

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

From the 30 seconds before the drug is started up to 60 seconds after it is consumed (except for the duration of the druguse)

Method of measurement

video taping

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Newborns who receive 24% sucrose through bolus dose in one step, two minutes before heel prick.

Category
Treatment - Drugs

2

Description
Intervention group 2:Newborns who receive 24% sucrose in three divided doses 2, 1.5 and 1 minutes before procedure.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu-Ali Sina hospital
Full name of responsible person
Mahkameh Soltani
Street address
Bu-Ali Sina hospital, Pasdaran street, Sari
City
Sari
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Mazandaran
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4815838477
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
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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
Sari 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
Mazandaran University of Medical Sciences
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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

Yes - There is a plan to make this available

Title and more details about the data/document

The data of the main outcome is published.

When the data will become available and for how long

Since publishing up to 3 months

To whom data/document is available

Only employees in academic centers

Under which criteria data/document could be used

If a researcher needs to do a more careful study on the data.

From where data/document is obtainable

It can be requested from the scientific responsible person.

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

After written request, it is examined and appropriate data is provided.

Comments