Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison survey between breast feeding and Sucrose on pain relief and physiological parameters during capillary sampling in neonates: A randomized controlled trial

Protocol summary

Summary

Objective: The aim of this study is to compare effects of breast feeding and sucrose in reducing pain during minimally invasive procedures in neonates such as capillary sampling. Design: Ninety-five consecutive infants who refer to Razavi Hospital, Mashhad for routine neonates screening will be selected. Participants: Ninety-five consecutive infants who underwent capillary sampling due to neonatal screening. Written informed consent should be filled by both parents. All the infants should meet inclusion criteria such as born at gestational age of ≥37 weeks; aged between 1-5 days and 5 minutes APGAR score of more than 7. Setting and interventions: Newborn infants will be divided to three groups: Group A: 2 ml sterile water as placebo; Group B: 2 ml sucrose 25% and Group C: breast feeding in kangaroo care.). Main outcome measures: Physiologic parameters including heart rate, blood pressure and capillary oxygen saturation level will be recorded during the sampling and 3 minutes after the procedure. NIPS score as well as physiologic values will be recorded by the investigator in each minute. Final result of NIPS score and physiologic values are the mean of given data for each 1-minute observation. Analysis will be done by means of SPSS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101919589N1**
Registration date: **2014-12-12, 1393/09/21**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-12-12, 1393/09/21

Registrant information

Name
Emadodin Darchini-Maragheh

Name of organization / entity
Mashhad University of Medical Sciences, Mashhad, Iran

Country
Iran (Islamic Republic of)

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+98 51 3878 6692

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad university of medical sciences, Mashhad, Iran

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison survey between breast feeding and Sucrose on pain relief and physiological parameters during capillary sampling in neonates: A randomized controlled trial

Public title

Effect of breast feeding and Sucrose on pain relief in

neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: filling the written informed consent by both parents; born at gestational age of ≥37 weeks; aged >24 hours (between 1-5 days); has 5 minutes APGAR score of ≥ 7 Exclusion criteria: Medically instable infants; those who had received sedatives or analgesics in the past 48 hours; infants who had received naloxone in the previous 24 hours; preterm and Low Birth Weight (LBW) infants; Those who had been fed in the past 30 minutes

Age

From **1 day** old to **5 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **95**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ethics committee, central building of Mashhad University of Medical Sciences (Ghorshi building), Daneshgah avenue, Mashhad, Iran

City

Mashhad

Postal code

Approval date

2014-10-19, 1393/07/27

Ethics committee reference number

938052

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

pain, not elsewhere classified

Primary outcomes

1

Description

heart rate

Timepoint

each minute until 3 minutes after sampling

Method of measurement

cardiac monitoring

2

Description

blood pressure

Timepoint

each minute until 3 minutes after sampling

Method of measurement

cardiac monitoring

3

Description

capillary oxygen saturation level

Timepoint

each minute until 3 minutes after sampling

Method of measurement

cardiac monitoring

4

Description

pain alleviating

Timepoint

each minute until 3 minutes after sampling

Method of measurement

neonatal infants pain scale score (NIPS)

Secondary outcomes

empty

Intervention groups

1

Description

2 ml of sterile water as placebo will be prepared and syringed in anterior part of the tongue 2 minutes before sampling

Category

Placebo

2

Description
2 ml sucrose 25% will be prepared in advance and syringed in anterior part of tongue 2 minutes before sampling
Category
Treatment - Other

3

Description
Infants will be breastfed in kangaroo care. Breastfeeding will be started 2 minutes before sampling and continue during the sampling. Infants are dressed, thus there is no skin to skin contact with mother. Mothers are not allowed to speak with their babies nor swaddle them.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razavi Hospital, NICU
Full name of responsible person
Dr. Anahita Alizadeh-Ghamsari
Street address
Azadi square, Ferdowsi university campus, medical university research center
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research- Mashhad University of Medical Sciences, Mashhad, Iran
Full name of responsible person
Dr. Tafaghodi
Street address
Research Department (Ghoreyshi building) - 2nd floor - Daneshgah Avenue
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research- Mashhad University of Medical Sciences, Mashhad, Iran
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Ferdowsi university campus, College of medicine
Full name of responsible person
Emadodin Darchini-Maragheh
Position
Medical student
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Medical toxicology research center, Imam Reza hospital, Imam Reza square, Mashhad
Full name of responsible person
Dr Anahita Alizadeh-Ghamsari
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MD, Pediatrician, fellowship of medical toxicology
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
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medical student
Other areas of specialty/work
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Medical toxicology research center, Ferdowsi university campus, Azadi square, Mashhad
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darchinime861@mums.ac.ir
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty