

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effect of breast-Milk and leg massage on neonate's pain intensity during Heel-blood sampling among hospitalized neonates in neonatal intensive care unit

Protocol summary

Summary

This study is a randomized crossover clinical trial aimed at comparing the effect of breast milk and leg massage on the pain intensity of 30 healthy neonates during a 2-phase heel-blood sampling in Neonatal Care Unit of Fayazbakhsh Hospital, Iran in 2016. This study is designed in such a way that each neonate included in the study will receive both interventions (leg massage and breast milk) with a 12-hour wash-out period between each of these interventions during which the baby does not receive any intervention. The neonates, based on randomly number schedule, are divided into two groups (leg massage and breast milk). In other words, each neonate undergoes two times of heel lance (left and right heel). Babies are placed in the supine position and heel lance is done by the researcher and intensity pain is determined based on the NIPS scale. The program of breastfeed group: Three ml of the breast milk taken 5 minutes before heel stick is poured in the baby's mouth slowly in drop by drop for 30 seconds. Then, the heel stick is done by the researcher and proceeded to determine the baby's pain during blood sampling and it goes through the NIPS scale for 2 minutes. Afterward, not any intervention is performed on neonate for 12 hours. Then, after breast milk program, the process of renewed heel lance on the other neonate heel is accomplished. The program of leg massage: Five minutes before the heel stick, the investigator slowly massages the outer aspect of the chosen leg for the heel stick from toes to mid thigh for 3 minutes by using a firm but gentle pressure with fingers and thumbs. After massage, the heel stick is done by the researcher.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062928696N1**

Registration date: **2016-10-12, 1395/07/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-12, 1395/07/21

Registrant information

Name

Afsane Afkhami

Name of organization / entity

Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 35 3724 0171

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of breast-Milk and leg massage on neonate's pain intensity during Heel-blood sampling among hospitalized neonates in neonatal intensive care unit

Public title

The effect of breast milk and leg massage on pain control in preterm neonates hospitalized in neonatal intensive care unit

Purpose

Other

Inclusion/Exclusion criteria

Inclusion: Premature baby with gestational age between 34-37 week, breast feeding, birth weight of 2kg and more, no respiratory distress, no surgery, One and five minutes Apgar score between 7-10, no congenital heart and enteric disease; healthy skin, no sepsis and intelligent neonate. Exclusion criteria: Unstable infant, those with head and skull deformities, congenital heart disease, cleft palate, cleft lip, and those who had received an analgesic in the 24 hours prior to sampling.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features

Randomization is done using random number table.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences.

Street address

Central building of Shahid Sadoughi University of Medical Sciences, Bahonar square

City

Yazd

Postal code

8916978477

Approval date

2016-06-08, 1395/03/19

Ethics committee reference number

IR.SSU.REC.1395.43

Health conditions studied**1****Description of health condition studied**

Pain

ICD-10 code

-

ICD-10 code description

-

Primary outcomes**1****Description**

Pain intensity

Timepoint

before, at the moment and after intervention

Method of measurement

NIPS scale

Secondary outcomes

empty

Intervention groups**1****Description**

The program of breastfeed group: Three ml of the breast milk taken 5 minutes before heel stick is poured in the baby's mouth slowly in drop by drop for 30 seconds. Then, the heel stick is done by the researcher and proceeded to determine the baby's pain during blood sampling and it goes through the NIPS scale for 2 minutes. Afterward, not any intervention is performed on neonate for 12 hours. Then, after breast milk program, the process of renewed heel lance on the other neonate heel is accomplished.

Category

Other

2**Description**

The program of leg massage: Five minutes before the heel stick, the investigator slowly massages the outer aspect of the chosen leg for the heel stick from toes to mid thigh for 3 minutes by using a firm but gentle pressure with fingers and thumbs. After massage, the heel stick is done by the researcher.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid fayaz bakhsh hospital

Full name of responsible person

Dr.Mohammad Hossein Gholizadeh

Street address

Khalije Fars street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahid Sadoughi University of Medical Sciences.

Full name of responsible person

Tahere Salimi

Street address

Nursing and Midwifing Faculty, Bou ali street, Yazd

City

Yazd

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 of Shahid Sadoughi University of Medical Sciences.

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

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Tahere Salimi

Position

MSC, The member of faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Social security organization

Full name of responsible person

Afsane Afkhami

Position

MSC student

Other areas of specialty/work

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Number 57 - Mehrdad bulding - Golha Ave - 1st bime street

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1391936481

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Web page address

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