Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the impact of mother’s gentle touch on the severity of pain caused by heel-prick blood sampling in premature infants admitted to the neonatal intensive care unit (NICU)

Protocol summary

Summary

Objectives: Investigating the impact of mother’s gentle touch on the severity of pain caused by heel-prick blood sampling in premature infants. Design: This study was a randomized clinical trial. Methodology: Using convenience sampling, 80 infants were selected from all the infants admitted to the Neonatal Intensive Care Unit of Ali ibn Abitalib Hospital, Zahedan and were randomly divided into two groups of 40 infants. The inclusion criteria: gestational age of 34-37 weeks, the fifth minute Apgar score of above six, hemodynamically stable condition, feeding half an hour before the intervention, receiving no sedative within the last 48 hours; availability and no history of addiction in mothers. The exclusion criteria: failed heel blood sampling in the first turn, increased baby's heart rate to above 180 beats per minute or decreased heart rate to below 100 beats per minute during the intervention; increased baby's respiratory rate to above 60 beats per minute or decreased respiratory rate to below 30 beats per minute during the intervention; decreased arterial O2 saturation to below 88%, during the intervention. Intervention: In the intervention group, half an hour before the heel blood sampling, babies were touched by their mothers [who had learned the gentle touch technique earlier] for 15 minutes and the control group received only the routine care. Based on the Neonatal Infant Pain Scale (NIPS), infants' behavioral responses to pain were measured and recorded, before, during and five minutes after the heel blood sampling. The main outcome variable: Neonatal pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014091510505N2**

Registration date: **2017-09-28, 1396/07/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-28, 1396/07/06

Registrant information

Name

Nasrin Mahmoodi

Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Zahedan University of Medical Sciences

Expected recruitment start date

2017-05-04, 1396/02/14

Expected recruitment end date

2017-11-20, 1396/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the impact of mother’s gentle touch on the severity of pain caused by heel-prick blood sampling in premature infants admitted to the neonatal intensive care unit (NICU)

Public title
The impact of mother’s gentle touch on the severity of pain experienced by premature infants
Purpose
Supportive
Inclusion/Exclusion criteria
The inclusion criteria: gestational age of 34-37 weeks; the fifth minute Apgar score of above six; hemodynamically stable condition; feeding half an hour before the intervention; receiving no sedative within the last 48 hours; availability and no history of addiction in mothers. The exclusion criteria: failed heel blood sampling in the first turn; increased baby's heart rate to above 180 beats per minute or decreased heart rate to below 100 beats per minute during the intervention; increased baby's respiratory rate to above 60 beats per minute or decreased respiratory rate to below 30 beats per minute during the intervention; decreased arterial O2 saturation to below 88%, during the intervention.
Age
From **1 day** old to **1 month** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zahedan University of Medical Sciences
Street address
Zahedan University of Medical Sciences, Fields of Dr. Hesabi, Zahedan, Iran
City
Zahedan
Postal code
9816913396
Approval date
2017-01-03, 1395/10/14
Ethics committee reference number
IR. ZAUMS. REC.1395.228

Health conditions studied

1

Description of health condition studied
Heel pain during blood sampling
ICD-10 code
M79.6
ICD-10 code description
Pain in limb

2

Description of health condition studied
preterm infants
ICD-10 code
P07.3
ICD-10 code description
Other preterm infants

Primary outcomes

1

Description
Pain in infants
Timepoint
Before, During and 5 minutes after intervention
Method of measurement
Neonatal Infant Pain Scale (NIPS)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group: In this group, each mother placed one hand’s fingertips over the eyeliner for 15 minutes and touched the premature baby’s forehead with her palm; while the other hand supported baby’s back and hips touched the lower abdomen.
Category
Prevention

2

Description
The control group: In this group, newborns received only the routine care and no other intervention was administrated.

Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali ibn Abi Talib Hospital
Full name of responsible person
Nasrin Mahmoodi
Street address
Mashahir Square, School of Nursing and Midwifery
City
Zahedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Zahedan University of Medical Sciences
Full name of responsible person
Dr. Rafighdoost Hoshang
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Research deputy of Zahedan University of Medical Sciences, Dr. Hesabi Squar Zahedan
City
Zahedan
Grant name
1
Grant code / Reference number
2456
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Zahedan 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

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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