

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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

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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 centers1**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 sources1**Sponsor****Name of organization / entity**

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Dr. Rafighdoost Hoshang

Street address

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**Contact****Name of organization / entity**

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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