

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of Kangaroo mother care on pain from heel lance in preterm newborns admitted to neonatal intensive care unit

Protocol summary

Summary

The purpose of this study was to assess the effect of kangaroo mother care on pain intensity of heel lance in preterm newborns admitted to neonatal intensive care units. In this cross over research, 64 vitally stable preterm infants between 30- 36 week gestational age admitted to neonatal intensive care units of Arash and Valiasr Hospitals affiliated to Tehran University of Medical Sciences and had need atleast two heel lance were randomly divided into two groups. In group A for the first heel lancing, infants recieved kangaroo care 15 minutes before the procedure. In group B, 15 minutes before lanceting, infants were kept in prone position, in incubator. For second heel lancing , the infants in group A were put in incubator, and group B received kangaroo care. Premature Infant pain profile (PIPP) were scored during and within 2 minutes after finishing the procedure in both conditions and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013030412702N1**

Registration date: **2013-10-28, 1392/08/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-10-28, 1392/08/06

Registrant information

Name

Maliheh Javidpour

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-06-23, 1391/04/03

Expected recruitment end date

2012-10-14, 1391/07/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Kangaroo mother care on pain from heel lance in preterm newborns admitted to neonatal intensive care unit

Public title

The effect of Kangaroo care on pain in preterm newborns

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: were newborns with gestational age of 30 -36 weeks; within 3 - 14 days of birth; breathing unassisted; did not have any congenital anomalies and central nervous system diseases; had not undergone surgery; and were not receiving paralytic; analgesic; or sedative medications within 48 hours; Mothers had to be willing and able to hold their infant in the KMC position for the study. Exclusion criteria: declining the mother from participation; discharging from the hospital before second heel lancing with written informed consent.

Age

From **30 years** old to **36 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

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

Single blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Gods Ave, Tehran

City

Tehran

Postal code

-

Approval date

2012-05-24, 1391/03/04

Ethics committee reference number

175/130/91/ۛ

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

Pain

ICD-10 code

R52.0

ICD-10 code description

Acute Pain

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

pain from heel lance

Timepoint

before, during and 2 minutes after the lancing

Method of measurement

PIPP was used

Secondary outcomes

empty

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

Kangaroo mother care position. In the Kangaroo mother care position, 15 minutes before, during and 2 minutes after the heel lancing, diaper-clad infant, was held upright, in skin to skin contact with their mother under her gown and between her breasts and a blanket were placed over the infant's back.

Category

Prevention

2**Description**

In incubator. In incubator condition, newborn were placed in the incubator in a prone position and swaddled with a blanket 15 minutes before, during and 2 minutes after the heel lancing.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Arash Hospital

Full name of responsible person

Javidpour Maliheh

Street address

Rashid Ave, Tehranpars, Tehran

City

Tehran

2**Recruitment center****Name of recruitment center**

Valiasr Hospital

Full name of responsible person

Javidpour Maliheh

Street address

Tohid Ave, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Rahmati Maryam

Street address

Faculty of Nursing and Midwifery, Tohid Av, Tehran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Emdadi Hospital

Full name of responsible person

Javidpour Maliheh

Position

MSC in Neonatal Intensive Care Nursing

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Mosayebi Ziba

Position

Neonatologist

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Javidpour Maliheh

Position

Master Degree of Neonatal Intensive Care Nursing

Other areas of specialty/work**Street address**

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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