

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of kangaroo mother care on premature newborns' pain due to invasive procedures

Protocol summary

Summary

Objective: To evaluate the effect of a kangaroo mother care on pain of invasive procedures in neonatal intensive care unit premature infants Hospital of Hamedan Fatemieh. Design: Quasi-experimental study. Manner: premature infants hospitalized in the neonatal intensive care unit hospital in Hamedan Fatemieh are eligible to enter the study sample will form. Inclusion criteria: infants without symptoms suggestive of severe disease or congenital abnormality that prevents him out incubator, do not, Age at birth of 32-37 weeks, according to records, no under ventilator and intubation, the export of doctor-specialist let newborn infant's hemodynamic stability for participating in the study, pulse oximetry during infant attachment studies. Exclusion criteria: existence or occurrence of any kind of medical or obstetric problem for maternal, infant death during the study, a factor which is not let the baby out of the incubator. Interventions: Kangaroo mother care method involves placing the baby in the mother's arms for 15 minutes before and after action. Primary outcome variables: the outcome of the pain that will be studied with the following methods: (a) Changes in infant pain behavior (facial pain, breathing pattern, legs, hands, level of consciousness) using NIPS pain scale for scoring. (b) Physiological changes (heart rate and arterial oxygen saturation) using pulse oximetry and a number of other physiological signs (pallor, facial flushing, sweating, palm sweating) With observing there is no in 3 stages before, during and after the offensive action will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021212455N1**

Registration date: **2013-02-25, 1391/12/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-02-25, 1391/12/07

Registrant information

Name

Maryam Pakseresht

Name of organization / entity

Hamadan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vic-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2013-03-05, 1391/12/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of kangaroo mother care on premature newborns' pain due to invasive procedures

Public title

Effect of kangaroo mother care on premature newborns' pain in neonatal intensive care unit

Purpose

Prevention

Inclusion/Exclusion criteria
 Premature infants hospitalized in the neonatal intensive care unit of Hamedan Fatemieh Hospital the following characteristics of the sample will be: A) Infants without symptoms suggestive of severe disease or congenital abnormality that prevents him out incubator.(B) Infants born 32-37 weeks of age, so the age is recorded in the file. (C) The infant ventilator and intube no. (c) Permit the physician to participate in a study of newborn infants based on hemodynamic stability. (d) Connecting newborn pulse oximetry during the study.Babies who have any of the following conditions will be excluded: (a) Existence or occurrence of any kind of medical or obstetric problems for the mother. (b) The baby died. (c) During the study, a factor which is not allowing the baby out of the incubator.

Age
 To **1 year** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **70**

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
 Local Human Subject Review board

Street address
 Hamadan University of Medical Sciences,Shahid Fahmideh Ave

City
 Hamadan

Postal code
 6517838695

Approval date
 2012-09-22, 1391/07/01

Ethics committee reference number
 16/35/9/4000/د/پ

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

Timepoint

Before, during and after invasive procedures

Method of measurement

Scale of pain and pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: kangaroo mother method of placing infants on the mother's chest for 15 minutes before and 15 minutes after invasive procedures

Category

Prevention

2

Description

Control: The control is not a specific intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Dr Fatemeh Cheraghi

Street address

Hamadan, Kermanshah Ave, Pasdaran

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic-Chancellor of Research and Technology, Hamadan
University of Medical Sciences

Full name of responsible person

Dr. Ahmad Tavilani

Street address

Hamadan University of Medical Sciences, Shaheed
Fahmideh Ave

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Hamadan

Grant name

از محل یک درصد بودجه پایان نامه های دانشگاه

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

Yes

Title of funding source

Vic-Chancellor of Research and Technology, Hamadan
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**

Hamadan University of Medical Sciences, Faculty of
Nursing and Midwifery, Department of Pediatrics

Full name of responsible person

Dr. Fatemeh Cheraghi

Position

PhD, Assistant

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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