

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparing effect of neonate's massage, kangaroo mother care and routine cares on neonates' physiological symptoms of pain due to invasive procedures in neonates

Protocol summary

Summary

This study aim to compare effect of neonate's massage, kangaroo mother care (KMC) and routine cares on hospitalized neonates' physiological symptoms of pain due to invasive procedures. This clinical trial study will conduct on 126 hospitalized term neonates in pediatric ward and NICU of Besat Hospital, Hamadan, Iran, during 2015. Inclusion criteria include lack of symptoms of severe disease or congenital abnormality that prevents neonate to exit from incubator; neonates who will born 32-37 weeks of age based on the age is recorded in the medical record and lack of intubation or connecting to ventilator in neonate. Exclusion criteria include existence or occurrence of any kind of medical or obstetric problems for the mother; neonate die during the study and any situation which do not allow to exit neonate from incubator. Subjects will divide to two intervention groups and one control group according to table of random numbers. In the first intervention group, KMC will perform for 30 minutes and in the second intervention group leg massage will do by mother for 15 minutes. In control group, while neonate is connecting to pulse oximetry in supine position will put in incubator without any touch and change in position. In both intervention groups, the physiological signs of pain in 15 minutes before invasive painful procedures (as minutes zero), during the invasive painful procedures (as minutes 15) and 15 minutes after the invasive painful procedures (as minutes 30) and in control group, in three same time as zero (15 minutes after supine position of neonate in the incubator), 15 (during a painful procedure) and 30 (15 minutes after painful procedures) will observe and record by physiological sign scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052914251N3**

Registration date: **2015-06-13, 1394/03/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-13, 1394/03/23

Registrant information

Name

MORTEZA NASIRI

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2015-04-01, 1394/01/12

Expected recruitment end date

2015-07-23, 1394/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of neonate's massage, kangaroo mother care and routine cares on neonates' physiological symptoms of pain due to invasive procedures in neonates

Public title

Effect of neonate's massage and kangaroo mother care on neonates' pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: lack of symptoms of severe disease or congenital abnormality that prevents neonates to exit from incubator; lack of any CNS abnormalities; lack of any obstetric or medical problems in mother; neonates who will born in 32-37 weeks of age based on the age is recorded in the medical record; lack of intubation or connecting to ventilator in neonates; approve of hemodynamic stability and allow to neonates participate in the study and exit from incubator by physician.

Exclusion criteria: existence or occurrence of any kind of medical or obstetric problems for the mother; neonate die during the study; any situation which do not allow to exit neonates from incubator.

Age

From **1 day** old to **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **126**

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

Hamadan University of Medical Sciences Ethics Committee

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave, Hamedan.

City

Hamadan

Postal code

Approval date

2015-03-02, 1393/12/11

Ethics committee reference number

16/35/9/6379/P

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

Pain scale and pulse oximetry

Secondary outcomes

1

Description

Heart rate

Timepoint

Before, during and after invasive procedures

Method of measurement

Pulse oximetry

2

Description

Oxygen saturation

Timepoint

Before, during and after invasive procedures

Method of measurement

Pulse oximetry

Intervention groups

1

Description

First intervention group: neonates will place on the mother's chest based on kangaroo mother method for 15 minutes before and 15 minutes after invasive procedures

Category

Prevention

2

Description

Second intervention group: neonates' leg will massage by mother in 15 minutes before and 15 minutes after invasive procedures

Category

Prevention

3

Description

Control group: while neonate is connecting to pulse oximetry in supine position will put in incubator without any touch and change in position.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital, Hamadan

Full name of responsible person

Maryam Valimalayeri

Street address

Besat Hospital, Mazghineh avenue, Hamadan

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Dr. Saied Bashirian

Street address

Hamadan University of Medical Sciences, Shaheed Fahmideh avenue

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Grant name

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 of 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

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

Full name of responsible person

Maryam Valimalayeri

Position

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Person responsible for updating data

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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