

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Effect of kangaroo mother care on premature infants's physiological indices and breastfeeding

Protocol summary

Summary

The aim of this study was to determine the effect of kangaroo mother care on premature infants' physiological indices and breastfeeding in the Fatemieh Hospital in Hamadan in 2015. A semi-experimental study will conduct among 100 premature neonates with gestational age between 32-36 weeks and weight less than 2500 grams. Infants who those mothers intend to kangaroo mother care (KMC) and stay in hospital will allocate in the intervention group. Mothers who do not intend to KMC and do not stay in hospital will allocate in the Control group. Two groups will match based on gestational age and weight. The infant in the intervention group receive KMC every day at least half an hour for four times. Physiological indices such as weight gain body temperature, oxygen saturation, pulse rate, respiratory rate, number of breastfeeding, infection, and length of hospitalization will assess daily. The infant in control group receive only routine care within the incubator and they will not remove from incubator except for feeding. In this group physiological indicators such as weight gain body temperature, oxygen saturation, pulse rate, respiratory rate, number of breastfeeding, infection, and length of hospitalization will assess three times in a day. Finally, two groups will compare from neonatal admission to discharge from hospital.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030310426N7**
Registration date: **2015-04-02, 1394/01/13**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-02, 1394/01/13

Registrant information

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2016-03-10, 1394/12/20

Expected recruitment end date

2016-03-10, 1394/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of kangaroo mother care on premature infants's physiological indices and breastfeeding

Public title

Effect of kangaroo mother care on premature infants' physiological indices and breastfeeding in the Fatemieh Hospital in Hamadan in 2015

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: low birth weigh; gestational age between 32-36 weeks without any congenital anomaly; stable newborn; physicians' permission to leave from incubator; without undergoing neonatal surgery; without photo-therapy; completed consent form their mother to participate of the study. Exclusion criteria: mother or infant conditions; illness and stressful events during the study such as NCPAP; breastfeeding contraindications.

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not 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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences- Shahid Fahmideh Street- Counterpoint of Mardom Park- Hamadan

City

Hamadan

Postal code

65178

Approval date

2015-03-02, 1393/12/11

Ethics committee reference number

p/16/35/9/6368

Health conditions studied

1

Description of health condition studied

Disorders related to short gestation and low birth weight,

not elsewhere classified

ICD-10 code

P07.3

ICD-10 code description

28 completed weeks or more but less than 37 completed weeks (196 completed days but less than 259 completed days) of gestation.

Primary outcomes

1

Description

Neonatal weight gain

Timepoint

Daily

Method of measurement

Balance Scale

2

Description

Physiological indices

Timepoint

Three times per day

Method of measurement

Termometer, Neonatal Monitoring Device

3

Description

Number of breastfeeding

Timepoint

Daily

Method of measurement

Observation

Secondary outcomes

1

Description

Neonatal infection

Timepoint

Daily

Method of measurement

Based on laboratory tests

2

Description

Lenght of hospitalization

Timepoint

Daily

Method of measurement

Observation

Intervention groups

1

Description

The infant in control group receive only routine care within the incubator and they will not remove from incubator except for feeding . In this group physiological indicators such as weight gain body temperature, oxygen saturation, pulse rate, respiratory rate, number of breastfeeding, infection, and length of hospitalization will assess three times in a day. Then, these indicators ob control group will compare with intervention group from neonatal admission to discharge from hospital.

Category

Other

2**Description**

The infant in the intervention group receive KMC every day at least half an hour for four times during a day . Physiological indices (such as weight gain body temperature, oxygen saturation, pulse rate, respiratory rate), number of breastfeeding, infection, and length of hospitalization will assess every day. The comparison will done between intervention group and control group from neonatal admission to discharge from hospital.

Category

Other

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

Nonatal Intensive Care Unite (NICU) in Fatemiah Hospital

Full name of responsible person

Dr. Behnaz Basiri

Street address

Fatemieh Hospital of Hamadan, Kermanshah street, Hamadan

City

Hamadan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Saied Bashirian

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Shahid Fahmideh Street- Counterpoint of Mardom ParkHamadan University of Medical Sciences-

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Hamadan

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

Yes

Title of funding source

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

Full name of responsible person

Dr. Parisa Parsa

Position

Asistant Professor / PhD

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

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Full name of responsible person

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Position

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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