Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 kangreoo 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 labratory 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

Street address

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

City

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

Research Center for Chronic Diseases Home Care, Hamadan University of Medicine and Health Sciences, Shahid Fahmideh Street- Counterpont of Mardom Park- Hamadan

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medicine and Health Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Assistant Professor/Ph.D

Other areas of specialty/work

Street address

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Person responsible for updating data

Contact
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Position
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Other areas of specialty/work
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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