Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparing the effects of conventional care and Kangaroo Mother Care on duration of hospitalization, weight gain, exclusive breastfeeding, and physiological measures in low birth weight neonates in intensive care unit

Protocol summary

Summary

Low birth weight significantly associated with infant mortality rate. Neonates in neonatal intensive care wards are separated from the mothers and lack of parental participation in care, have many risks and threats. Kangaroo Mother Care(KMC) is identified as alternative methods of care that can help to reduce these risks and threats. Kmc method cause better communication of parents and infants, improve weight gain in preterm infants, early discharge, reduction of nosocomial infection, develop exclusive breastfeeding, reduce hospital costs, cause more parental participation in care and better infant growth and development . Methods: This study was a semi-experimental clinical trial in which a researcher examine effects of independent variables (kmc care, Incubator care) on the dependent variables (body temperature, weight gain, exclusive breastfeeding, physiological measures) in 130 low birth weight infants admitted to neonatal intensive care in Tehran Mahdieh hospital (2009-2010). Since the success of kmc implementation and follow-up for the proper function and protection of mothers related to doctors and personnel knowledge and experience, the importance and necessity of training courses in this respect is obvious.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010204982N1**
Registration date: **2011-01-31, 1389/11/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-01-31, 1389/11/11

Registrant information

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Recruitment status

Recruitment complete

Funding source

researcher

Expected recruitment start date

2009-06-02, 1388/03/12

Expected recruitment end date

2011-03-02, 1389/12/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of conventional care and Kangaroo Mother Care on duration of hospitalization, weight gain, exclusive breastfeeding, and physiological measures in low birth weight neonates in intensive care unit

Public title

Kangaroo care in premature neonates

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1. without congenital anomalies 2. Birth weight between 2499-1200 grams. 3. fifth minute Apgar score is six and higher. 4. not having respirator care in the past 12 hours 5. not used umbilical arterial catheter 6. not used Photo therapy in previous 4 hours ago 7. the baby's body temperature is not unstable. 8. 8 hours out of the endotracheal tube 9. not having chest tube 10. not having symptoms of respiratory distress .For mothers of neonates, inclusion criteria were : 1- familiar with Persian language. 2- not having malignant disease and fever 3- not having addiction and smoking – 4- not having AIDS and acute respiratory and heart disease 5- being biological mother. 6- not having convulsions or seizure disorders 7- having self-care ability. Exclusion criteria: 1-Mother refusing 2-Apnea more than 20 second.

Age

To **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **130**

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

Tehran university of medical sciences

Street address

Enghelab street

City

Tehran

Postal code

0098

Approval date

2010-12-11, 1389/09/20

Ethics committee reference number

1115/130/89/د

Health conditions studied

1

Description of health condition studied

Disorders related to short gestation and low birth weight

ICD-10 code

P07.3

ICD-10 code description

Other preterm infants

Primary outcomes

1

Description

Weight gain

Timepoint

DAILY

Method of measurement

scale

2

Description

Body temprature

Timepoint

During daily kangaroo mother care

Method of measurement

Termometr

3

Description

Infection

Timepoint

According to sign and symptom

Method of measurement

Laboratory

4

Description

Exclusive breast feeding

Timepoint

Persistant

Method of measurement

Look

5

Description

Respiratory problems

Timepoint

All of the time of care

Method of measurement

Palsoximetry

6

Description

Pulse rate

Timepoint

During kangaroo care

Method of measurement

control Machine

Secondary outcomes

1

Description

Hospitalisation days

Timepoint

After releasing

Method of measurement

Days number

Intervention groups

1

Description

kangaroo care or KMC

Category

Prevention

2

Description

Incubator care

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr.Saree

Street address

Enghelab street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, 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

Ministry of health and medical education

Full name of responsible person

Dr.Soheila Khazaei

Position

associate professor

Other areas of specialty/work

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Full name of responsible person
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Position
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