Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of duration of Kangaroo mother care (KMC) method on the growth of low birth weight neonate

Protocol summary

Summary

This is the first study to assess the effectiveness of Kangaroo Mother Care (KMC) for infants of low birth weight < 2500g in Iran. We will monitor the effect of Kangaroo Mother Care (KMC) for less than four hours intervals on the body weight, temperature, blood oxygen saturation, nursing frequency, infection disease and death of low weight newborn in Fatemiey hospital neonatal intensive care during year 2012. If this study shows that KMC with less than four hrs intervals is more effective than KMC care for more than four hrs intervals, this method will find more acceptance in neonatal intensive care and the shortening of space and resources won't stops the mothers to use this method. We will study 120 low birth weight new born, 60 will be in a group of Kangaromother care. The impact of the duration of the intervention will be evaluated on indicators of weight, body temperature and, daily feeding with milk, the risk of infection and mortality assessment.

General information

Acronym

KMC

IRCT registration information

IRCT registration number: **IRCT2012072810420N1**
Registration date: **2012-12-17, 1391/09/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-12-17, 1391/09/27

Registrant information

Name

Shohre Heidari Farah

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0033

Email address

sh.heidari@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of duration of Kangaroo mother care (KMC) method on the growth of low birth weight neonate

Public title

Comparison the effect of duration of the method of Kangaroo mother care (KMC) on the growth of low birth weight neonate

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: 1. neonates with weight less than 2500 grams; 2. condition for exit neonate from the incubator and care by the mother; 3. Neonate has not a congenital anomaly or neuromuscular disorder, neonate does not have surgery and not phototherapy. Exclusion criteria: 1. problems not-related to the care during the study; 2. If the parents of the neonate, for any reason and at any

time, desire to withdraw from the study.

Age
From **1 year** old to **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

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
Hamedan University of Medical Sciences

Street address
Shahid Fahmideh street

City
Hamedan

Postal code
65178

Approval date
2012-06-11, 1391/03/22

Ethics committee reference number
1030/9/35/16/پ/د

Health conditions studied

1

Description of health condition studied
Low birth weight neonate

ICD-10 code
E40-46

ICD-10 code description
Malnutrition

Primary outcomes

1

Description
Breast Feeding

Timepoint
1st, 2nd, 5th, 7th days

Method of measurement
Observation

2

Description
Weight gain

Timepoint
1st, 3rd, 5th and 7th days

Method of measurement
weighting scale

3

Description
chanhe in temperature

Timepoint
1st day, 3rd day, 5th day

Method of measurement
termometer

Secondary outcomes

1

Description
The length of inpatient hospitalization

Timepoint
1 month after hospitalization

Method of measurement
phone call

2

Description
Sepsis

Timepoint
during hospitalization

Method of measurement
Blood cultuer

Intervention groups

1

Description
Less than 4 hours kangaroo mother care

Category
Behavior

2

Description
More than 4 hours kangaroo mother care

Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh hospital
Full name of responsible person
Shohre Heidari Farah
Street address
Shahid Fahmide Street
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Heidar tavilani
Street address
Shahid fahmide strit
City
Hamedan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Shohre Heidari Farah
Position
MD
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Behnaz Basiri
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Neonatology Specialist
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact
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Hamedan University of Medical Sciences
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Shohre Heidari Farah
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MD
Other areas of specialty/work
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Hamedan Besat Hospital
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Hamedan
Postal code
65178
Phone
+98 81 1264 0033
Fax
Email
sh.heidari@umsha.ac.ir
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