

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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 Fatemiyeh 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 stop 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/د/پ

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

change in temperature

Timepoint

1st day, 3rd day, 5th day

Method of measurement

thermometer

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 culture

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**Street address**

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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

Position

Neonatology Specialist

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

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Web page address

Person responsible for updating data

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Full name of responsible person

Shohre Heidari Farah

Position

MD

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65178

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Fax**Email**

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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