

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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 newborn, 60 will be in a group of Kangaroo mother 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**

Hamedan Besat hospital

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+98 81 1264 0044

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sh.heidari@umsha.ac.ir

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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**

Hamedan Fatemieh hospital

**City**

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+98 81 1827 7012

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**Web page address**

## Person responsible for updating data

#### 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**

Hamedan Besat Hospital

**City**

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*