

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jul 2026

### Comparison of Kangaroo mother care and conventional method in premature of less than 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections

#### Protocol summary

##### Summary

Objective: The aim of study was to compare the effect of Kangaroo mother care (KMC) and conventional methods of care (CMC) in premature low birth weight babies less than 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections. Method: One hundred babies with birth weight less than 2000 grams and without clinical problem will randomly divided in two groups, the intervention group (N=50) receive Kangaroo mother care and the control group (N=50) receive conventional care. Two groups will compare in daily weight gaining, self confidence of mother, duration of hospitalization, clinical cyanosis and nosocomial infections.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201101091162N16**

Registration date: **2011-02-10, 1389/11/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-02-10, 1389/11/21

##### Registrant information

###### Name

Ashraf Mohammadzadeh

###### Name of organization / entity

Neonatal Research Center of Mashhad University of  
Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1852 1121

###### Email address

mohamadzadeha@mums.ac.ir

###### Recruitment status

**Recruitment complete**

###### Funding source

Mashhad university of medical sciences

###### Expected recruitment start date

2007-03-07, 1385/12/16

###### Expected recruitment end date

2009-01-31, 1387/11/12

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of Kangaroo mother care and conventional method in premature of less than 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections

###### Public title

Comparison of Kangaroo mother care and conventional method in premature of less 2000 grams birth weight in weight gaining, clinical cyanosis, mother confidence, hospitalization and nosocomial infections

###### Purpose

Prevention

###### Inclusion/Exclusion criteria

Inclusion criteria: Babies with birth weight less than 2000 gr which were stabilized in first 72 hr of age Exclusion criteria: babies with requiring ventilator support,

suffering from apnea, unstable temperature, and intravenous nutrient

#### Age

From **2 years** old to **28 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice chancellor for research of Mashhad University of medical sciences

##### Street address

Ghoreshi building, Daneshgah street

##### City

Mashhad

##### Postal code

13131-91379

#### Approval date

2006-12-26, 1385/10/05

#### Ethics committee reference number

11471/51

## Health conditions studied

### 1

#### Description of health condition studied

nosocomial infection

#### ICD-10 code

Y95

#### ICD-10 code description

Nosocomial condition

### 2

#### Description of health condition studied

duration of hospitalization

#### ICD-10 code

Z59.3

#### ICD-10 code description

Problems related to living in residential institution

### 3

#### Description of health condition studied

weight gaining

#### ICD-10 code

R62.8

#### ICD-10 code description

Other lack of expected normal physiological development

### 4

#### Description of health condition studied

self confidence of mother

#### ICD-10 code

F69

#### ICD-10 code description

Unspecified disorder of adult personality and behaviour

### 5

#### Description of health condition studied

cyanosis

#### ICD-10 code

R23.0

#### ICD-10 code description

Cyanosis

## Primary outcomes

### 1

#### Description

weight gaining

#### Timepoint

daily

#### Method of measurement

with scale

### 2

#### Description

mother confidence

#### Timepoint

daily

#### Method of measurement

clinical

### 3

#### Description

hospitalization

#### Timepoint

daily

#### Method of measurement

at discharge

#### 4

**Description**

cyanosis

**Timepoint**

daily

**Method of measurement**

clinical

#### 5

**Description**

nosocomial infections

**Timepoint**

daily

**Method of measurement**

positive culture of blood, CSF, Urine

### Secondary outcomes

#### 1

**Description**

temperature instability

**Timepoint**

q 6 hours

**Method of measurement**

with thermometer

### Intervention groups

#### 1

**Description**

kangaroo mother care

**Category**

Prevention

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

neonatal research center of Mashhad university of medical sciences

**Full name of responsible person**

Dr.Ashraf Mohammadzadeh

**Street address**

Neonatal research center- NICU- Emamreza hospital

**City**

Mashhad

### Sponsors / Funding sources

#### 1

**Sponsor****Name of organization / entity**

Mashhad university of medical sciences

**Full name of responsible person**

Dr Jalil Tavakol Afshari

**Street address**

Ghoreshi bulding, Daneshgah street

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Neonatal Research Center

**Full name of responsible person**

Dr. Ashraf Mohammadzadeh

**Position**

Neonatologist, professor

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

NRC-NICU-Emamreza hospital

**City**

Mashhad

**Postal code**

9137913316

**Phone**

+98 51 1852 1121

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**Email**

mohamadzadeha@mums.ac.ir

**Web page address**

www.mums.ac.ir/nrc

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Neonatal Research Center

**Full name of responsible person**

Dr.Ashraf Mohammadzadeh

**Position**

Neonatologist, professor

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

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Neonatal Research Center

**Full name of responsible person**

Dr.Ashraf Mohammadzadeh

**Position**

Neonatologist, professor

**Other areas of specialty/work**

**Street address**

NRC-NICU-Emaereza hospital

**City**

Mashhad

**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*