

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Effects of Kangaroo mother care on neonates and their mothers who delivered by cesarean section

#### Protocol summary

##### Summary

This study evaluate the effect of Kangaroo Contact (KC) on some physiological and neurobehavioral responses of the term newborns and mothers pain profile in Fatemiye hospital in Shahrood-Iran. In a randomized controlled trail, 160 mother-infant dyads will be recruited in KC and routine care (RC) groups. In intervention group, KC will be done three 60 min/day for 2 consecutive days. After cesarean section (C/S), Pain intensity will be determined by verbal numeric analogue scale (0-10 score) in all women. Temperature will be observed in four sets for each neonate. Mean of reflexes score, incidence of jaundice and urine cortizol in newborns will be compared between two groups. Before discharge, the rate of satisfaction in mothers will be gathered by a checklist. Two groups will be followed for exclusive breastfeeding until six months postpartum.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138806172324N2**

Registration date: **2009-09-08, 1388/06/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2009-09-08, 1388/06/17

##### Registrant information

###### Name

Maryam Keshavarz

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4365 1813

##### Email address

keshavarz@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahrood University of medical sciences and health services

##### Expected recruitment start date

2007-09-28, 1386/07/06

##### Expected recruitment end date

2008-09-20, 1387/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Kangaroo mother care on neonates and their mothers who delivered by cesarean section

##### Public title

Effects of Kangaroo mother care in neonates and their mothers

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria : Iranian women with single and term pregnancy, 18-40 years old, with history of cesarean section delivery (only general anesthesia in current C/S); No pre-existing medical complications or obstetrics complications in current pregnancy, divorce , unwilling neonate's sex, history of psychiatric illness or illicit drug use; also healthy neonate with no need to resuscitation or hospitalization in NICU. Exclusion criteria: unwilling to continuing of intervention, neonate admission in NICU.

##### Age

From **21 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **160**

**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**

Shahrood University of medical sciences and health services

**Street address**

Haft tir square

**City**

Shahrood

**Postal code**

**Approval date**

2007-07-13, 1386/04/22

**Ethics committee reference number**

8605

**Health conditions studied**

1

**Description of health condition studied**

mothers and neonate in cesarean section unit- kangaroo mother care

**ICD-10 code**

82.8

**ICD-10 code description**

Other single delivery by caesarean section

**Primary outcomes**

1

**Description**

Neurobehavioral response of Term neonate

**Timepoint**

daily

**Method of measurement**

urine cortisol , check list and questionnaire

2

**Description**

Decrease in pain profile in mothers

**Timepoint**

daily

**Method of measurement**

visual analoge pain scale

**Secondary outcomes**

1

**Description**

Exclusive Breast Feeding

**Timepoint**

6 months after delivery

**Method of measurement**

check list

**Intervention groups**

1

**Description**

Kangaroo mother care

**Category**

Prevention

2

**Description**

Routine care

**Category**

N/A

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Fatemiyeh hospital

**Full name of responsible person**

Maryam Keshavarz

**Street address**

Bistodo Bahman street

**City**

Shahrood

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Shahrood University of medical sciences and health services

**Full name of responsible person**

Maryam Keshavarz

**Street address**

Haft Tir square

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Shahrood

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahrood University of medical sciences and health services

**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**

Nursing and Midwifery, Iran University of Medical Sciences

**Full name of responsible person**

Maryam Keshavarz

**Position**

MSc in midwifery - academic member

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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