

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Effect of Kangaroo mother care (KMC) and conventional methods (CMC) of care on response to pain second to Hepatitis B vaccination

#### Protocol summary

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#### Summary

The aim of this study was to compare the effect of Kangaroo mother care (KMC) and conventional methods (CMC) of care on response to pain secondary to Hepatitis B vaccination. A total of 40 preterm neonates between 32-37 weeks of gestational age, who are clinically stable, were randomly assigned into 2 groups. During vaccination against hepatitis B, in the intervention group (20 newborns) received KMC and the control group (20 newborns) received CMC. Response to pain with oxygen saturation by pulsoxymetry, pulse rate with monitoring, duration of crying by timer and pain score by NIPS test were compared between groups.

#### Recruitment status

**Recruitment complete**

#### Funding source

Mashhad University of Medical Sciences

#### Expected recruitment start date

2009-03-12, 1387/12/22

#### Expected recruitment end date

2010-02-09, 1388/11/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT201104211162N17**

Registration date: **2011-06-10, 1390/03/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2011-06-10, 1390/03/20

#### 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

#### Scientific title

Effect of Kangaroo mother care (KMC) and conventional methods (CMC) of care on response to pain second to Hepatitis B vaccination

#### Public title

Effect of Kangaroo mother care (KMC) and conventional methods (CMC) of care on response to pain second to Hepatitis B vaccination

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: newborn between 32-37 weeks gestational age, normal general condition, no respiratory problems, Apgar score above 7 and without congenital malformation Exclusion criteria: cardiac and respiratory problems, congenital anomalies, hemodynamic problems, infants treated with sedative or analgesic drugs and usage of narcotics or sedatives by mother

#### Age

From **2 years** old to **15 years** old

#### Gender

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 40

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

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**

2010-08-20, 1389/05/29

**Ethics committee reference number**

511/2364

**Health conditions studied****1****Description of health condition studied**

Kangaroo mother care

**ICD-10 code****ICD-10 code description****2****Description of health condition studied**

Vaccination

**ICD-10 code****ICD-10 code description****3****Description of health condition studied**

Response to pain

**ICD-10 code**

R52.9

**ICD-10 code description**

Pain, unspecified

**Primary outcomes****1****Description**

Oxygen saturation

**Timepoint**

From 2 min before to 3 min after intervention

**Method of measurement**

pulsoxymetry

**2****Description**

Heart rate

**Timepoint**

From 2 min before to 3 min after intervention

**Method of measurement**

Cardiac monitoring

**3****Description**

Crying duration

**Timepoint**

From 2 min before to 3 min after intervention

**Method of measurement**

timer

**4****Description**

response to pain

**Timepoint**

From 2 min before to 3 min after intervention

**Method of measurement**

NIPS test

**Secondary outcomes**

empty

**Intervention groups****1****Description**Kangaroo mother care, During the vaccination, baby was  
laid as cuddling in own mother.**Category**

Prevention

**2****Description**lying baby in bed, During the vaccination in control group  
baby was laid on bed.**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**

NRC-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 building, 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**

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## Person responsible for scientific inquiries

### Contact

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

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## Person responsible for updating data

### Contact

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**Position**

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

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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*