

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Paternal vs Maternal Kangaroo and routine care for pain relief in preterm neonates

#### Protocol summary

##### Summary

Purpose: Comparison of the effect of paternal and maternal kangaroo care vs. routine care on pain relief premature after heel stick in the neonatal intensive care  
Inclusion criteria: Infant with 28-37 gestational age; not having any congenital anomaly  
Exclusion criteria: Infants undergoing mechanical ventilation; approached both of parents. The study population premature infant with gestational age 28-37 weeks. The study sample size is 240 infants that these infants must at least have 3 times blood sample according to doctor order, all infants get 3 interventions. Primary Outcome: relief of pain At the beginning of study before the heel lance infants had been selected randomly in permuted blocks in paternal kangaroo care (KC) and maternal KC and incubator (routine care). Then place the infant in the KC position and incubator would maintain that position before, during, and at least 15 minutes after the procedure. Close-up video recordings of the infants' faces were made using a 1 Sony camera with tripod set (so that the viewer just sees eyebrows and eyes, nose and mouse except parent's arms and incubator). At this time skilled and research nurse blood procurement from heel with a blue lancet; Film recordings were made for 1 minute in three situation (father, mother, incubator) for the first baseline, 1 minute before the start of the heel lance procedure while in KC and in incubator for the second baseline, and during and after the procedure. At the end the obtained film from pulse oxymeter and neonates' faces will analyzed by PIPP.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120217972N4**

Registration date: **2015-03-15, 1393/12/24**

Registration timing: **na**

Last update:

Update count: **0**

##### Registration date

2015-03-15, 1393/12/24

##### Registrant information

###### Name

Zahra Godarzi

###### Name of organization / entity

School of Nursing and Midwifery, Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6105 4407

###### Email address

godarziz@tums.ac.ir

##### Recruitment status

**Not enough for processing**

##### Funding source

Deputy for Research Tehran University of Medical Sciences

##### Expected recruitment start date

2014-09-23, 1393/07/01

##### Expected recruitment end date

2014-01-20, 1392/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Paternal vs Maternal Kangaroo and routine care for pain relief in preterm neonates

##### Public title

Paternal vs Maternal Kangaroo and routine care for pain relief in preterm neonates after heel lancet procedure

## Purpose

Supportive

## Inclusion/Exclusion criteria

Preterm neonates born between 28 and 36 weeks gestational age who were expected to stay in the neonatal intensive care unit for at least 3 blood sampling procedures; body temperature stability between 36/3-36/9; Infant with apgar first minutes more than 6; without hypoglycemia and any congenital anomaly; No needs to oxygen therapy in all study time; approached parents; Not having central venous line; Infant nutrition with breast feeding or formula milk; Not using sedative drugs at past 24 hours  
Exclusion criteria: No more than one time blood sampling procedures in each day; Restless baby; Infants undergoing mechanical ventilation; refuse parents to participate in the study

## Age

From **7 months** old to **9 months** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **240**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee in research Tehran University Of Medical Sciences

##### Street address

Room 501. Fifth Floor, Medical Ethics and History of Medicine Reserch Center. Junction of Qhods st and Keshavarz Boulevard

##### City

tehran

##### Postal code

#### Approval date

2014-06-10, 1393/03/20

#### Ethics committee reference number

93/D/130/1303

## Health conditions studied

### 1

#### Description of health condition studied

Preterm Infant

#### ICD-10 code

P07

#### ICD-10 code description

28 Completed weeks or more but less than 37

## Primary outcomes

### 1

#### Description

Pain caused by heel blood sampling

#### Timepoint

Before lancet handling:While lancet handling:After lancet handling

#### Method of measurement

Premature infant pain profile

## Secondary outcomes

### 1

#### Description

Changes in heart rate

#### Timepoint

One minute before the lancet-During Lancet-after lancet

#### Method of measurement

Pipp

### 2

#### Description

Change in o2 saturation

#### Timepoint

Before lancet-During Lancet-after lancet

#### Method of measurement

Premature infant pain profile

## Intervention groups

### 1

#### Description

Intervention group:kangaroo father care! kangaroo mother care

#### Category

Other

### 2

#### Description

Control group: Routin care or incubatore

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Valiasr Hospital

**Full name of responsible person**

Zahra Godarzi

**Street address**

Emam Khomini Hospital , Keshavarz Bulvard, Tehran

**City**

Tehran

### 2

#### Recruitment center

**Name of recruitment center**

Arash Hospital

**Full name of responsible person**

Zahra Godarzi

**Street address**

NO 162, Abdolmajid Aveneu , Baghdarnia Street,  
Tehranpars, Tehran

**City**

tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Deputy of Research Tehran University Of Medical  
Sciences

**Full name of responsible person**

Dr Masoud Yunesian

**Street address**

Room 604, Sixth Floor, Central Organization Of  
Tehran University Of Medical Sciences, Qhods St,  
Keshavarz Boulevard

**City**

Tehran

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

Yes

**Title of funding source**

Deputy of Research Tehran 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

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University Of Medical Sciences School Of  
Nursing And Midwifery

**Full name of responsible person**

Zahra Godarzi

**Position**

Faculty Member of Nursing School

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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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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*