Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Boulvard
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 handeling؛While lancet handeling؛After lancet handeling
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 Siences 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
Tehran Faculty Nursing & Miwifery. Eastern Nosrat St، Doctor Mirkhani St، Tohid Square
City
Tehran
Postal code
Phone
+98 21 6105 4407
Fax
Email
godarziz@tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tehran University Of Medical Sciences School Of Nursing And Midwifery
Full name of responsible person
Fatemeh Rabani
Position
Student Of Neonatal Intensive Care Nursing
Other areas of specialty/work
Street address
No 65 ، Fifth Floor، Ahadzadeh Alley، Tehranpars ، Tehran
City
Tehran
Postal code
1685753661
Phone
+98 21 7729 2292
Fax
Email
Rabani_nurse@yahoo.com
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