

Alternative Female Kangaroo Care: an intervention to reduce pain response in preterm neonates (28 - 36 weeks)

Submission date 19/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/07/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

A09-B33-06A

Study information

Scientific Title

Alternative Female Kangaroo Care: an intervention to reduce pain response in preterm neonates (28 - 36 weeks)

Acronym

AFKC

Study objectives

Primary hypothesis:

There will be no difference in pain response and time to recovery from heel lance in 28 - 36 weeks gestational age Neonatal Intensive Care Unit (NICU) preterm neonates when they are engaged in maternal Kangaroo Care (KC) compared to when they are engaged in Alternative Female Kangaroo Care (AFKC).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Study approved by McGill University Institutional Review Board (IRB) on 11th September 2006 (ref: A09-B33-06A).

Study design

This study is a test of non-inferiority or alternate mother KC versus maternal KC. It is a crossover design where neonates served as their own control.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Pain response

Interventions

After obtained informed consent from the mother and the alternative female, the neonate will be randomised to:

1. Control group: mother first and alternative female second, or
2. Treatment group: alternative female first and mother second

Kangaroo Care involves placing a diaper-clad neonate at an angle of sixty degrees between the breasts providing maximal skin-to-skin contact between the infant and the caregiver. The neonate is placed in KC for 15 minutes before the painful procedure (heelstick) performed by a

hospital technician assigned to the study. The alternative female will wear a mask if she did not visit her general practitioner for good health within two days of the treatment condition.

All alternate females will wash their chest with a non-scented soap common to the NICU and will respect the hand washing procedures recommended by the NICU. The heel-lance procedure is relatively standardised across staff and timing and is an aspect of routine care for hospitalised preterm neonates. Each neonate will have two KC sessions filmed; one with the mother and one with the alternative female. The measures will be taken for the entire heel-lance procedure (one minute baseline, one minute warming of the neonate's foot, stick, extraction of the blood and return to baseline).

Second sponsor:

Canadian Nurses Foundation (Canadian Nurses Foundation [CNF])

50 Driveway

Ottawa, Ontario

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Canada

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Pain measured with Premature Infant Pain Profile (PIPP)
2. Facial actions of the PIPP scored according to Neonatal Facial Coding System (NFCS)

Secondary outcome measures

Time for return to physiological baseline measured as the preterm neonate's return to baseline Heart Rate (HR) after the heel lance procedure procured via an oximeter placed on the unaffected foot of the neonate.

Overall study start date

11/09/2006

Completion date

11/09/2008

Eligibility

Key inclusion criteria

1. Born between 28 0/7 weeks and 36 6/7 gestational age
2. Obtained consent
3. Receiving at least two heel lances prior to discharge
4. Within 10 days of hospitalisation
5. Neonate has to be stable according to the Neonatal Intensive Care Unit criteria
6. Alternate female had to be healthy and older than 18 years old

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

N = 64, power = 0.8, alpha = 0.05 using the PIPP with a difference of 1 point of the PIPP scale.

Total final enrolment

18

Key exclusion criteria

Does not comply with the inclusion criteria.

Date of first enrolment

11/09/2006

Date of final enrolment

11/09/2008

Locations

Countries of recruitment

Canada

Study participating centre

3506 University, room 226

Montreal

Canada

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Sponsor information

Organisation

Montreal Inter-University Group for Nursing Research (GRISIM) (Canada)

Sponsor details

3875, rue St-Urbain

Bureau 205

Montreal
Canada
H2W 1V1

Sponsor type

Research organisation

Website

<http://www.grisim.ca/index.php?L=1>

Funder(s)

Funder type

Research organisation

Funder Name

Quebec Health Research Fund (Fonds de recherche en Santé du Québec [FRSQ])/Montreal Inter-University Group for Nursing Research (Groupe de Recherche Interuniversitaire en Sciences Infirmières de Montréal [GRISIM]) (Canada)

Funder Name

Canadian Nurses Foundation (Canadian Nurses Fondation [CNF]) (Canada)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/11/2012	19/07/2021	Yes	No