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

Submission date	Recruitment status	[_] Prospectively registered
19/07/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/10/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/07/2021	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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 practioner for good health within two days of the treatment condition.

All alternate females will wash their chest with an 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 Fondation [CNF])

50 Driveway
Ottawa, Ontario
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Intervention Type
Other

Phase
Not Specified

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

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
H3A 2A7

Sponsor information

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

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

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