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Kangaroo Care with Father's protocol: an intervention to reduce pain response in preterm neonates (28 - 36 weeks gestation)

Submission date 16/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/03/2009	**Overall study status** Completed	
Last Edited 02/11/2011	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2580; MOP-64307

Study information

Scientific Title
Kangaroo Care with Father's protocol: an intervention to reduce pain response in preterm neonates (28 - 36 weeks gestation): a randomised controlled crossover trial

Acronym
FKC

Study objectives
There will be a difference in pain response, time to recovery and heart rate variability (HRV) 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 father's KC.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CHU St-Justine Research Ethics Board (REB) gave approval on the 16th July 2007 (ref: 2580)

Study design
Randomised controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Pain response during heel lancing

Interventions
After obtained informed consent from the mother and the father, the neonate will be randomised to intervention (father first mother second) or control (mother first father second). Kangaroo care involves placing a diaper-clad neonate at an angle of sixty degrees between the breasts or on the chest providing maximal skin-to-skin contact between the infant and the

caregiver. The neonate is placed in KC 15 minutes before the painful procedure (heel lance) performed by a hospital technician assigned to the study. 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 the other one with the father. The measures will be taken for the entire heel lance procedure (one minute of baseline isolette, one minute of baseline kangaroo, one minute of warming, extraction of the blood and return to baseline kangaroo and isolette.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain measured with Premature Infant Pain Profile (PIPP), repeated over 30 second blocks
2. Facial actions of the PIPP scored according to Neonatal Facial Coding System (NFCS)

Secondary outcome measures
Timing for return to physiologic baseline measured as the preterm neonate's return to baseline HR after the heel lance procedure procured via an oximeter placed on the unaffected foot of the neonate.

Overall study start date
01/10/2007

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Born between 28 0/7 and 35 6/7 weeks of gestation, either sex
2. Obtained consent
3. Receiving at least two heel lances prior to discharge
4. Within 10 days of hospitalisation
5. Stable according to Neonatal Intensive Care Unit criteria

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
80

Key exclusion criteria
1. Genetic or major congenital disorders
2. Requiring surgery before or during the study period
3. Receiving analgesics or paralysing agents
4. Intra-ventricular haemorrhage (IVH) grade III+ or periventricular leukomalacia (PVL) as confirmed by ultrasound

Date of first enrolment
01/10/2007

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
Canada

Study participating centre
3506 University, room 226
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Sponsor information

Organisation
McGill University (Canada)

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Sponsor type
University/education

Website
http://www.mcgill.ca

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (Canada) - http://www.cihr-irsc.gc.ca (ref: MOP-64307)

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	results	01/09/2011		Yes	No