

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

<b>Submission date</b> 16/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 31/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/11/2011	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**  
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

**Study type(s)**

Treatment

**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(s)**

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)

**Key secondary outcome(s)**

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.

**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

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

1. Genetic or major congenital disorders
2. Requiring surgery before or during the study period
3. Receiving analgesics or paralyzing 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  
Montreal  
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## Sponsor information

**Organisation**  
McGill University (Canada)

**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

**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?
<a href="#">Results article</a>	results	01/09/2011		Yes	No