

# Maternal kangaroo care for procedural pain in very preterm neonates

<b>Submission date</b> 26/03/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/06/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/03/2009	<b>Condition category</b> Pregnancy and Childbirth	<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**  
MOP-64307

## Study information

**Scientific Title**  
Maternal comfort, analgesia, regulation, endorphin-release: mothercare, a program of research for pain in critically ill infants and toddlers

**Acronym**  
MotherCARE

**Study objectives**

Preterm infants less than 32 weeks post-menstrual age (pma) will have greater physiologic stability and decreased salivary cortisol response to heel stick procedure during skin-skin contact than prone in isolette.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved by McGill University Health Centre (full board review) on 20th November 2003 (ref: MCH003-48)

**Study design**

Randomised cross-over design

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Physiologic stability in preterm infants

**Interventions**

Skin-to-skin contact: the diaper-clad infant will be held upright at an angle of sixty degrees between the breasts of the mother during a routine heel stick procedure. A blanket will be placed over the infants back throughout the intervention. The baby will remain in this condition for 15 minutes prior to heel lance, during the procedure and until the infant returns to baseline heart rate after the procedure is completed. In the control group, the infant will be in the prone position in the isolette.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Physiologic stability:

1. Maximum range of heart rate and O2 saturation from baseline throughout the procedure
2. Time to return to baseline heart rate and O2 saturation

**Key secondary outcome(s))**

Stress response: measured through the procurement of salivary cortisol collected prior to (basal) and 30 minutes after (stress response) the heel stick procedure for both the mother and the infant

**Completion date**

01/01/2006

# Eligibility

## Key inclusion criteria

Infants born between 28 0/7 and 32 6/7 weeks pma as determined by an ultrasound will be eligible

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Child

## Sex

All

## Key exclusion criteria

1. Genetic or major congenital disorders
2. Requiring surgery before or during the study period
3. Receiving analgesics, paralysing agents or steroid therapy
4. Apgar scores less than 6 at five minutes
5. Intraventricular haemorrhage (IVH) grade III and/or periventricular leukomalacia (PVL) as confirmed by ultrasound

## Date of first enrolment

01/12/2003

## Date of final enrolment

01/01/2006

# Locations

## Countries of recruitment

Canada

## Study participating centre

3506 University Street

Montreal

Canada

H3A 2A7

# Sponsor information

**Organisation**

McGill University (Canada)

**ROR**

<https://ror.org/01pxwe438>

**Funder(s)****Funder type**

Research organisation

**Funder Name**

Canadian Institute 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	24/04/2008		Yes	No