

# Enhanced MotherCARE for procedural pain in preterm neonates

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

**Contact name**  
Dr Celeste Johnston

**Contact details**  
3506 University Street  
Room 226  
Montreal  
Canada  
H3A 2A7

## 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**  
Enhanced MotherCARE

**Study objectives**

Physiological pain and stress response will be lower in maternally enhanced skin-skin contact (SSC) than SSC in preterm neonates of 32 - 36 weeks.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

McGill University Health Centre (full board review) approved on the 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**

Pain response

**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.

Maternally-enhanced skin-skin contact: throughout the procedure, the mother will be seated with her infant in a rocking chair and will be asked to recite rhymes or sing songs to her infant. This will begin 15 minutes prior to heel stick. Just before the heel stick procedure, she will be asked to insert the tip of her well-trimmed smallest finger into the baby's mouth for the baby to suck. One minute later, the procedure will begin by collecting baseline data.

**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**

01/12/2006

## Eligibility

**Key inclusion criteria**

Infants born between 28 0/7 and 32 6/7 weeks post-menstrual age (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, paralyzing 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**

01/12/2006

## 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	01/01/2009		Yes	No