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Enhanced MotherCARE for procedural pain in preterm neonates

Submission date 26/03/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 27/06/2006	**Overall study status** Completed	
Last Edited 27/03/2009	**Condition category** Pregnancy and Childbirth	

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/12/2003

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

Age group
Child

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, 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)

Sponsor details
3506 University Street
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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 Institute 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	01/01/2009		Yes	No