Enhanced MotherCARE for procedural pain in preterm neonates

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

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

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?
Results article	results	01/01/2009		Yes	No