

Maternal kangaroo care for procedural pain in very preterm neonates

Submission date 26/03/2006	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 27/06/2006	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 27/03/2009	Condition category Pregnancy and Childbirth	☐ 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?
Results article	results	24/04/2008		Yes	No