

Kangaroo Care with Father's protocol: an intervention to reduce pain response in preterm neonates (28 - 36 weeks gestation)

Submission date 16/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 31/03/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 02/11/2011	Condition category Signs and Symptoms	<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, room 226
Montreal, QC
H3A 2A7
Montreal
Canada
H3A 2A7
+1 514 398 4157
celeste.johnston@mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

Kangaroo Care with Father's protocol: an intervention to reduce pain response in preterm neonates (28 - 36 weeks gestation): a randomised controlled crossover trial

Acronym

FKC

Study objectives

There will be a difference in pain response, time to recovery and heart rate variability (HRV) from heel lance in 28 - 36 weeks gestational age Neonatal Intensive Care Unit (NICU) preterm neonates when they are engaged in maternal kangaroo care (KC) compared to when they are engaged in father's KC.

Ethics approval required

Old ethics approval format

Ethics approval(s)

CHU St-Justine Research Ethics Board (REB) gave approval on the 16th July 2007 (ref: 2580)

Study design

Randomised controlled crossover trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Pain response during heel lancing

Interventions

After obtained informed consent from the mother and the father, the neonate will be randomised to intervention (father first mother second) or control (mother first father second). Kangaroo care involves placing a diaper-clad neonate at an angle of sixty degrees between the breasts or on the chest providing maximal skin-to-skin contact between the infant and the

caregiver. The neonate is placed in KC 15 minutes before the painful procedure (heel lance) performed by a hospital technician assigned to the study. The heel lance procedure is relatively standardised across staff and timing and is an aspect of routine care for hospitalised preterm neonates. Each neonate will have two KC sessions filmed; one with the mother and the other one with the father. The measures will be taken for the entire heel lance procedure (one minute of baseline isolette, one minute of baseline kangaroo, one minute of warming, extraction of the blood and return to baseline kangaroo and isolette).

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Pain measured with Premature Infant Pain Profile (PIPP), repeated over 30 second blocks
2. Facial actions of the PIPP scored according to Neonatal Facial Coding System (NFCS)

Secondary outcome measures

Timing for return to physiologic baseline measured as the preterm neonate's return to baseline HR after the heel lance procedure procured via an oximeter placed on the unaffected foot of the neonate.

Overall study start date

01/10/2007

Completion date

01/04/2009

Eligibility**Key inclusion criteria**

1. Born between 28 0/7 and 35 6/7 weeks of gestation, either sex
2. Obtained consent
3. Receiving at least two heel lances prior to discharge
4. Within 10 days of hospitalisation
5. Stable according to Neonatal Intensive Care Unit criteria

Participant type(s)

Patient

Age group

Neonate

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 or paralysing agents
4. Intra-ventricular haemorrhage (IVH) grade III+ or periventricular leukomalacia (PVL) as confirmed by ultrasound

Date of first enrolment

01/10/2007

Date of final enrolment

01/04/2009

Locations**Countries of recruitment**

Canada

Study participating centre

3506 University, room 226

Montreal

Canada

H3A 2A7

Sponsor information**Organisation**

McGill University (Canada)

Sponsor details

c/o Dr Celeste Johnston

School of Nursing

3506 University, Room 226

Montreal

Canada

H3A 2A7

+1 514 398 4157

celeste.johnston@mcgill.ca

Sponsor type

University/education

Website

<http://www.mcgill.ca>

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes 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	01/09/2011		Yes	No