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Touch and Talk for Procedural Pain in Infants and Toddlers in the Paediatric Intensive Care Unit (PICU)

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

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
Touch and Talk (T&T)

Study objectives
Infants and children who are critically ill will be more physiologically stable during line removal and will have heart rates (HR) and O2 saturation rates return to baseline sooner when mothers use touch and talk (T&T) versus no maternal contact with the child.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill University Health Centre (full board review) approved on 20/11/2003 (ref: MCH003-48).

Study design
A crossover design with each child as their own control. Order of condition will be randomly assigned.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain response

Interventions
Mothers will be taught where to sit so they can hold their child's hand during one line removal. They will be encouraged to talk to their child, either reciting nursery rhymes, signing or speaking in baby talk to children less than two years or for the other children, reading a story or talking about the child's favorite things. Then at the time of the child's line removal, the mother will provide T&T during one line removal but not the other.
The control group will receive no maternal contact.

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
Children from full-term birth through to three years are eligible, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
1. Infants born less than full term
2. Children older than three years
3. Children receiving paralytic agents

Date of first enrolment
01/11/2005

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 Institutes 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