

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

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

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 Street
Room 226
Montreal
Canada
H3A 2A7

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

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

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

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 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

01/11/2005

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

Age group

Child

Sex

Both

Target number of participants

66

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)

Sponsor details

3506 University Street

Room 226

Montreal

Canada

H3A 2A7

Sponsor type

University/education

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