ISRCTN13204272 https://doi.org/10.1186/ISRCTN13204272

Therapeutic Touch for procedural pain in preterm neonates less than 28 weeks gestational age

Submission date
13/03/2006

Recruitment status
No longer recruiting

Registration date
22/09/2006

Overall study status
Completed

Last Edited
07/01/2021

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Montreal
Canada
H3A2A6

Additional identifiers

Protocol serial number
CAM 06-315

Study information

Scientific Title
Therapeutic Touch for procedural pain in preterm neonates less than 28 weeks gestational age

Acronym
TT- Therapeutic Touch

Study objectives
1. Infants receiving Therapeutic Touch (TT) will show a lower pain score (Premature Infant Pain Profile [PIPP]) in response to heel lance for blood sampling for clinical purposes.
2. Infants receiving TT will have a shorter recovery (return to baseline heart rate) from heel lance for blood sampling for clinical purposes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, McGill University, Faculty of Medicine, approval given on the 27/07 /2005.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preterm infant pain

Interventions
Therapeutic Touch (TT) is a non-invasive method used in other populations to calm and comfort. TT is a form of energy therapy provided by a trained practitioner. The practitioner uses the hands to assess and rebalance the energy field of the patient.

In the control group, the therapist stands at the incubator with their hands at the side and performs mental math calculations. This is neither a sham therapeutic touch nor usual care, in that therapist will actually be standing beside the patient, behind screen to keep the condition masked for those caring for the infant.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Pain response (measured by the Premature Infant Pain Profile)

Key secondary outcome(s)
Return to baseline heart rate

Completion date
31/05/2007

Eligibility

Key inclusion criteria
Infants hospitalised in a Neonatal Intensive Care Unit (NICU) and parents are aware of the study and provide full informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Severe birth asphyxia
2. Major congenital anomalies requiring surgery
3. Currently receiving opioid analgesia or sedatives

Date of first enrolment
01/06/2006

Date of final enrolment
31/05/2007

Locations

Countries of recruitment
Canada

Study participating centre
3506 University
Montreal
Canada
H3A2A6

Sponsor information

Organisation
SickKids Foundation (Canada)

ROR
https://ror.org/04374qe70

Funder(s)

Funder type
Charity

Funder Name
SickKids Foundation (CAM 06-315)

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	01/09/2013	07/01/2021	Yes	No