

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

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| Submission date 13/03/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 22/09/2006 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 07/01/2021 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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.

Study design

Randomised controlled trial

Primary study design

Interventional

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 |