

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

**Submission date**  
13/03/2006

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
22/09/2006

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
07/01/2021

**Condition category**  
Pregnancy and Childbirth

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet****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 measure**

Pain response (measured by the Premature Infant Pain Profile)

**Secondary outcome measures**

Return to baseline heart rate

**Overall study start date**

01/06/2006

**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

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

52 infants

**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)

**Sponsor details**

525 University Avenue

14th Floor

Toronto

Canada

M5G 2L3

**Sponsor type**

Charity

**Website**

<http://www.sickkidsfoundation.com>

**ROR**

<https://ror.org/04374qe70>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

SickKids Foundation (CAM 06-315)

## **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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 01/09/2013   | 07/01/2021 | Yes            | No              |