ISRCTN23411530 https://doi.org/10.1186/ISRCTN23411530

Effectiveness of sucrose analgesia in reducing pain responses in infants born to diabetic and non-diabetic mothers: A randomized controlled trial

Submission date
15/08/2005

Recruitment status
No longer recruiting

Registration date
15/08/2005

Overall study status
Completed

Last Edited
28/01/2019

Condition category
Signs and Symptoms

[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00213213

Secondary identifying numbers
MCT-63143

Study information

Scientific Title
Effectiveness of sucrose analgesia in reducing pain responses in infants born to diabetic and non-diabetic mothers: A randomized controlled trial

Study objectives
1. Administration of sucrose analgesia for every painful cutaneous procedure performed after delivery will result in less pain during the newborn infant screening test performed by venipuncture prior to hospital discharge
2. Sucrose analgesia for every painful cutaneous procedure will decrease pain responses in infants undergoing repeated heel lancing
3. Administration of sucrose for every painful procedure will not be associated with adverse effects
4. Administration of sucrose for every painful procedure will decrease anticipatory pain responses during venipuncture for the newborn screening test
5. There is a relationship between previous painful procedures and infant response during routine care procedures

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mount Sinai Hospital Research Ethics Board 17/06/2003

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Pain responses in infants born to diabetic mothers

Interventions
Group 1: 2 ml of 24% sucrose (weight/vol) 2 minutes prior to all noxious tissue-damaging cutaneous procedures
Group 2: 2 ml of sterile water (placebo) 2 minutes prior to all noxious tissue-damaging cutaneous procedures

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sucrose

Primary outcome measure
Infant pain score during venipuncture for the newborn screening test, as assessed by the Premature Infant Pain Profile (PIPP), or individual parameters of PIPP if there is divergence in response between parameters.

Secondary outcome measures
Secondary outcomes (effectiveness):
1. Effectiveness of sucrose for repeated heel lances
2. Effectiveness of sucrose in decreasing anticipatory pain responses during venipuncture
3. Determination of relationship between painful procedures and infant response during routine care procedures

Secondary outcomes (safety):
1. Incidence of vomiting during drug administration
2. Oxygen saturation during drug administration
3. Serum Glucose concentrations in infants of diabetic mothers

Overall study start date
01/07/2003

Completion date
31/07/2006

Eligibility

Key inclusion criteria
Include healthy newborn infants ≥36 weeks gestation (either sex). There are 2 study strata: infants born to mothers with diabetes (type 1, type 2, or gestational diabetes that is diet-controlled or insulin-dependent), and infants born to non-diabetes mothers with uneventful pregnancies.

Participant type(s)
Patient

Age group

Neonate

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Admission to the neonatal intensive care unit (NICU)
2. Plan to undergo circumcision during the study period
3. Major congenital or neurological anomalies
4. Clinical diagnosis of birth asphyxia or seizures
5. Receiving analgesics or sedatives

Date of first enrolment
01/07/2003

Date of final enrolment
31/07/2006

Locations

Countries of recruitment
Canada

Study participating centre
Department of Pharmacy
Toronto, Ontario
Canada
M5G 1X8

Sponsor information

Organisation
Hospital for Sick Children, Toronto (Canada)

Sponsor details
555 University Avenue
Toronto, Ontario
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/057q4rt57

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-63143)

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?
Results article	results	01/07/2008	28/01/2019	Yes	No