

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
15/08/2005	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
15/08/2005	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
28/01/2019	Signs and Symptoms	

## 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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## Additional identifiers

### ClinicalTrials.gov (NCT)

NCT00213213

### Protocol serial number

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

## Study type(s)

Prevention

## 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(s)**

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.

### **Key secondary outcome(s)**

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

### **Completion date**

31/07/2006

## **Eligibility**

### **Key inclusion criteria**

Include healthy newborn infants  $\geq$ 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

### **Healthy volunteers allowed**

No

### **Age group**

Neonate

### **Sex**

All

### **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

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## Sponsor information

**Organisation**

Hospital for Sick Children, Toronto (Canada)

**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

**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	01/07/2008	28/01/2019	Yes	No