

Minimizing needle poke pain in newborn infants with a pain relieving cream and sugar water

Submission date 22/08/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 23/08/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/04/2008	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MCT-82947

Study information

Scientific Title
Evaluation of liposomal lidocaine and oral sucrose for treatment of pain in newborn infants undergoing venipuncture: a randomised controlled trial

Study objectives

Public title: Minimising needle poke pain in newborn infants with a pain relieving cream and sugar water

Hypothesis 1: Sucrose plus liposomal lidocaine will be superior to either agent alone in reducing pain during venipuncture.

Hypothesis 2: Plasma levels of lidocaine will be below toxicologically significant levels (1 mcg /ml), providing objective evidence of safety.

Hypothesis 3: Plasma levels of endomorphins-1,-2 will be higher in infants pre-medicated with sucrose versus lidocaine, confirming that sucrose exerts its analgesic effects via an opioid-mediated mechanism.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was gained from the Research Ethics Board of Mount Sinai Hospital Toronto, Ontario, Canada on August 03, 2007 (ref: 07-0099-A).

Study design

Randomised, controlled, double-dummy, single-centre, three arm trial with study participant and investigator, caregiver, outcome assessor, and data analyst blinded.

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Newborns undergoing painful procedure

Interventions

Experimental arm one: 1 g of liposomal lidocaine to the dorsum of hand for 30 - 40 minutes prior to venipuncture and 2 ml of placebo water by mouth using a syringe over 1 - 2 minutes prior to venipuncture.

Experimental arm two: 2 ml of 24% sucrose administered by mouth using a syringe over 1 - 2 minutes prior to venipuncture and 1 g of placebo liposomal lidocaine to the dorsum of hand for 30 - 40 minutes prior to venipuncture.

Experimental arm three: both 1 g of liposomal lidocaine to the dorsum of hand for 30 - 40 minutes prior to venipuncture and 2 ml of 24% sucrose administered by mouth using a syringe over 1 - 2 minutes prior to venipuncture.

Due to double dummy, all infants receive oral sucrose or water (placebo) and all infants receive liposomal lidocaine or placebo. Each baby gets one intervention (experimental arm 1, 2, or 3).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Liposomal lidocaine, oral sucrose

Primary outcome(s)

Infant pain during venipuncture as assessed by facial grimacing response - the score will incorporate three facial actions: brow bulge, eye squeezed shut, naso-labial furrow, during venipuncture.

Key secondary outcome(s)

1. Visual Analog Scale (VAS), during venipuncture
2. Cry duration, during venipuncture
3. Heart rate, during venipuncture
4. Number of attempts until procedure completion, from first needle poke to completion
5. Endomorphins -1, -2, levels, before and 10 minutes after sucrose/sucrose placebo administration
6. Procedure duration, from first needle poke to completion
7. Lidocaine levels, 5 - 15 minutes after the liposomal lidocaine cream/placebo cream is removed

Completion date

28/02/2010

Eligibility**Key inclusion criteria**

All healthy full-term (greater than 37 weeks gestational age) newborn infants (either sex)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Neonatal Intensive Care Unit (NICU) admission
2. Asphyxia, seizures
3. Major birth defects (heart, brain, genetic syndrome)
4. Circumcised during study
5. Receiving analgesia/sedatives

Date of first enrolment

01/08/2007

Date of final enrolment

28/02/2010

Locations

Countries of recruitment

Canada

Study participating centre

Department of Pharmacy and Child Health Evaluative Sciences

Toronto, Ontario

Canada

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Sponsor information

Organisation

The Hospital for Sick Children (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-82947)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration