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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/08/2007

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

Age group

Neonate

Sex
Both

Target number of participants
330

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
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Sponsor information

Organisation
The Hospital for Sick Children (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.sickkids.ca/

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

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