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Sucrose as Procedural Analgesia for Infants Receiving Venipuncture in a Pediatric Emergency Department

Submission date	Recruitment status	[_] Prospectively registered
12/08/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/07/2007	Signs and Symptoms	

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
N/A

Study information

Scientific Title

Acronym
SWEET Study

Study objectives
Pain scores will be significantly reduced for infants who either recieve sucrose, pacifier or both prior to venipuncture as compared to placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pain

Interventions
Patients are randomly assigned to one of four groups as follows:
a. Sucrose orally (PO)
b. Sucrose PO & pacifier
c. Placebo PO
d. Placebo PO & pacifier

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Score on the Faces Legs Arms Crying and Consolability (FLACC) Scale

Secondary outcome measures
Crying Time, Heart Rate

Overall study start date
01/03/2004

Completion date
30/06/2005

Eligibility

Key inclusion criteria
Any infant 0-6 months requiring venipuncture as part of their emergency department management

Participant type(s)
Patient

Age group
Child

Lower age limit
0 Months

Upper age limit
6 Months

Sex
Both

Target number of participants
132

Key exclusion criteria
Infants deemed too critically ill or otherwise ineligible at the discretion of the attending physician

Date of first enrolment
01/03/2004

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Canada

Study participating centre
Room 7217B, Second Floor
Edmonton, Alberta
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T6G 2J3

Sponsor information

Organisation
University of Alberta, Department of Pediatrics (Canada)

Sponsor details
Aberhart Centre One
11402 University Avenue
Edmonton, Alberta
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Sponsor type
University/education

Website
http://www.med.ualberta.ca/pediatrics/

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
University/education

Funder Name
Department of Pediatrics, University of Alberta

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:	18/07/2007		Yes	No