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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Sarah Curtis

Contact details

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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 Canada T6G 2J3

Sponsor information

Organisation

University of Alberta, Department of Pediatrics (Canada)

Sponsor details

Aberhart Centre One 11402 University Avenue Edmonton, Alberta Canada T6G 2J3

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