

4% Ametop gel to reduce procedural pain in infants receiving a percutaneously inserted central catheter (PICC)

Submission date 18/11/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/11/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/03/2009	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

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
FRN: 59754

Study information

Scientific Title

How effective is 4% Ametop gel applied before a percutaneously inserted central catheter (PICC) in reducing procedural pain in infants: a randomised placebo controlled trial

Study objectives

To compare multidimensional pain scores as measured with the premature infant pain profile (PIPP) during insertion of a PICC in infants randomised to Ametop (Ametocaine) or placebo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Ottawa Hospital Research Ethics Board gave approval on the 27th June 2002.

Study design

Randomised placebo controlled trial

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

Procedural pain in premature infants

Interventions

Treatment group: Amethocaine 4% gel, 1.5 g, applied for 30 minutes before the PICC insertion

Placebo group: placebo gel (professional skin care lotion, Smith-Nephew), 1.5 g applied for 30 minutes before the PICC insertion

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Ametop

Primary outcome measure

Premature Infant Pain Profile (PIPP) score at 1 minute

Secondary outcome measures

1. PIPP scores at 1, 2, 3 and 4 minutes after the PICC
2. Physiological indicators of pain (HR, SaO₂, BP, RR) at 1, 2, 3, 4, 5 and 10 minutes
3. Duration of cry in seconds from PICC insertion to recovery, number of attempts and success rate at inserting the PICC.
4. Safety: local skin reaction (redness, edema), significant changes in the complete blood count (CBC), alanine aminotransferase (ALT), aspartate aminotransferase (AST) and creatinine before (within 48 hours) and after (within 48 hours) the intervention

Overall study start date

18/12/2002

Completion date

26/07/2004

Eligibility**Key inclusion criteria**

1. Born at greater than or equal to 24 weeks gestation
2. Infants 24 - 40 weeks gestational age, either sex
3. With skin considered in good condition (no burns or rash)
4. When less than 27 weeks gestation, must be greater than or equal to 48 hours of life
5. Considered stable by treating neonatologist
6. With informed consent by a parent or legal guardian

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

54

Key exclusion criteria

1. Skin considered immature
2. Suspected or proven significant central nervous system anomaly
3. Infants receiving opioids or sedatives at time of PICC insertion or in the previous 12 hours or infants receiving muscle relaxants
4. Infants with facial anomalies preventing typical facial expression of pain
5. Infants with sub optimal hepatic function (alanine aminotransferase [ALT] 2 x upper normal limit) or sub-optimal renal function
6. Parents or legal guardian have refused consent

Date of first enrolment

18/12/2002

Date of final enrolment

26/07/2004

Locations

Countries of recruitment

Canada

Study participating centre

401 Smyth Road

Ottawa

Canada

K1H 8L1

Sponsor information

Organisation

Childrens Hospital of Eastern Ontario Research Institute (CHEORI) (Canada)

Sponsor details

401 Smith Rd

Ottawa

Canada

K1H 8L1

Sponsor type

Hospital/treatment centre

Website

<http://www.cheori.org/>

ROR

<https://ror.org/05nsbhw27>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: FRN: 59754)

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	03/05/2006		Yes	No