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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/11/2005	**Overall study status** Completed	
Last Edited 06/03/2009	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Brigitte Lemyre

Contact details
401 Smyth Road
Ottawa
Canada
K1H 8L1
blemyre@ottawahospital.on.ca

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, Sa02, 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