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How effective is Ametop 4% gel, before a venipuncture, at reducing procedural pain in infants: a randomized placebo-controlled trial

Submission date	Recruitment status	[_] Prospectively registered
29/07/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/11/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/10/2022	Signs and Symptoms	

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
BL 002

Study information

Scientific Title
How effective is Ametop 4% gel, before a venipuncture, at reducing procedural pain in infants: a randomized placebo-controlled trial

Study objectives
Amethocaine 4% gel applied before a venipuncture in newborn infants will safely and significantly decrease procedural pain

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Procedural pain

Interventions
Ametop (amethocaine) 4% gel versus placebo, 1.5 g applied to skin for 30 minutes prior to the venipuncture

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ametop (amethocaine, tetracaine hydrochloride) 4% gel

Primary outcome measure

Premature Infant Pain Profile (PIPP) score in the first minute after skin puncture

Secondary outcome measures
1. PIPP scores during the first, second, third and fourth minute post-skin puncture
2. Mean heart rate in beats per minute, mean respiratory rate per minute, mean blood pressure in mm Hg and mean 02 saturation in % at the end of baseline, 1 minute after skin puncture then 2, 3, 4, 5 and 10 minutes after skin puncture
3. Duration of cry, from skin puncture to recovery
4. Ease of procedure, as reflected by the mean number of attempts required to obtain the bloodwork, the success rate at obtaining the bloodwork and subjective measure of easiness on a scale of 1 to 5 (1 being very easy and 5 very hard)

The safety of amethocaine was assessed using the following data: local skin reaction (redness, edema), complete blood count and differential (pre and post intervention), aspartate aminotransferase (AST) and ALT (pre and post intervention), and creatinine levels (post intervention). All infants' vital signs were monitored throughout and after the intervention and any significant event (apnea/bradycardia, sustained bradycardia or tachycardia, sustained desaturation requiring intervention) was recorded.

Overall study start date
03/01/2003

Completion date
30/12/2004

Eligibility

Key inclusion criteria
1. Born at >24 weeks gestation
2. Skin considered in good condition (no burns or rash)
3. If <27 weeks gestation, at least 48 hours of life
4. Considered stable by the treating neonatologist

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
54

Total final enrolment
142

Key exclusion criteria

1. Skin considered immature (insensible water losses requiring more fluids than usual for gestation)
2. Suspected or proven significant central nervous system anomaly
3. Receiving opioids or sedatives at time of venipuncture or in the previous 12 hours or receiving muscle relaxants
4. Facial anomalies (cleft lip/palate, Moebius syndrome) preventing typical facial expression of pain
5. Sub optimal hepatic function (alanine aminotransferase [ALT] >2 x upper normal limit) or sub optimal renal function (urine output <1 ml/kg/hour in the last 12 hours)

Date of first enrolment
03/01/2003

Date of final enrolment
30/12/2004

Locations

Countries of recruitment
Canada

Study participating centre
401 Smyth Road
Ottawa
Canada
K1H 8L1

Sponsor information

Organisation
Children's Hospital of Eastern Ontario Research Institute (Canada)

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

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/05nsbhw27

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Physicians Services Incorporated (#02-39) and Children's Hospital of Eastern Ontario Research Institute

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		08/02/2007	27/10/2022	Yes	No