

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

Submission date 29/07/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 04/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 27/10/2022	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

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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 O2 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.

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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

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