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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**
29/07/2005

**Recruitment status**
No longer recruiting

**Registration date**
04/11/2005

**Overall study status**
Completed

**Last Edited**
27/10/2022

**Condition category**
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

**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

## Study design
Randomised controlled trial

## Primary study design
Interventional

## 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 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.

### 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
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## 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 |