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# Optimising local anaesthesia for grommet insertion

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 30/09/2004 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/09/2004 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/10/2009 | Ear, Nose and Throat | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr A E Camilleri

**Contact details**
Clinical Director and Consultant ENT surgeon
University Hospital of South Manchester Foundation Trust
Alexandra BMI Hospital,
University of Manchester
Manchester
United Kingdom
M23 9LT
+44 (0)161 217 3734
andrew.camilleri@uhsm.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0226132778

# Study information

### Scientific Title

### Study objectives
To determine which of the two local anaesthetic agents i.e. EMLA (Eutectic mixture of local anaesthetics) or Ametop (topical amethocaine) provides better local anaesthetic effect during grommet insertions

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Provided by South Manchester Research Ethics Committee

### Study design
Double blind randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied
Ear, Nose and Throat: Grommet insertions

### Interventions
EMLA (Eutectic mixture of local anaesthetics) or Ametop (topical amethocaine) for grommet insertion

### Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)

mixture of local anaesthetics or topical amethocaine

### Primary outcome measure
Measuring pain on visual analogue score

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
15/11/2003

### Completion date
15/11/2004

## Eligibility

### Key inclusion criteria
40 patients over 18 years of age requiring grommet insertion under local anaesthetic

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### Target number of participants
40

### Key exclusion criteria
Added 19/10/09: children and adult patients not willing to sign consent form.

### Date of first enrolment
15/11/2003

### Date of final enrolment
15/11/2004

## Locations

### Countries of recruitment
England

United Kingdom

**Study participating centre**
**Clinical Director and Consultant ENT surgeon**
Manchester
United Kingdom
M23 9LT

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
South Manchester University Hospitals NHS Trust (UK)

# 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 | 01/08/2008 | | Yes | No |