

# Optimising local anaesthesia for grommet insertion

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/10/2009	<b>Condition category</b> Ear, Nose and Throat	<input type="checkbox"/> 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**  
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

**Study type(s)**

Treatment

**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(s)**

Measuring pain on visual analogue score

**Key secondary outcome(s)**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Not Specified

**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**

United Kingdom

England

**Study participating centre**

**Clinical Director and Consultant ENT surgeon**

Manchester

United Kingdom

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**Sponsor information****Organisation**

Department of Health

**Funder(s)**

**Funder type**  
Government

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

## Results and Publications

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?
<a href="#">Results article</a>	results	01/08/2008		Yes	No