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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

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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
M23 9LT

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?
Results article	results	01/08/2008		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes