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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