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A randomised comparison of two techniques for inflation of the Classic Laryngeal Mask Airway (CLMA) during anaesthesia

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/06/2015	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0212157341

Study information

Scientific Title
A randomised comparison of two techniques for inflation of the Classic Laryngeal Mask Airway (CLMA) during anaesthesia

Study objectives
Is there any difference in performance of the Laryngeal Mask Airway (LMA) when using either of the 2 techniques of cuff inflation described?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bath Research Ethics Committee, 24/03/2005, ref: 05/Q2001/31

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Surgery: Anaesthesia

Interventions
Technique 1 vs technique 2 for inflation of the Classic Laryngeal Mask Airway (CLMA) during anaesthesia

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

Added 22/07/2008:
1. Airway seal pressure
2. Composite measures of adequacy of airway device placement

Secondary outcome measures
Added 22/07/2008:
1. Composite measures to assess functional adequacy of airway device
2. Volume of air in LMA cuff at on removal
3. Initial cuff pressure after syringe inflation
4. Composite measures of pharyngeal trauma

Overall study start date
24/02/2005

Completion date
01/07/2008

Eligibility

Key inclusion criteria
Adult patients presenting to RUH for day case and minor in-patient operations who meet the inclusion criteria for the trial and who are to be anaesthetised by any of the investigators.
All patients who are having an anaesthetic where the CLMA would be expected to be the airway used are suitable to be recruited. We will study 130 adult patients (American Society of Anaesthesiologists physical status 1 - 3 age >16 years) undergoing non-emergency surgery in the supine or lithotomy position under general anaesthesia with spontaneous respiration during maintenance of anaesthesia.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Aiming for 130 patients

Key exclusion criteria
1. Patients will not be studied if they have any pathology of the neck
2. At risk of pulmonary aspiration of gastric contents
3. Unable to understand the study or give informed consent to take part
4. We will not study patients weighing less than 35 kg or greater than 120 kg

Date of first enrolment
24/02/2005

Date of final enrolment
01/07/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal United Hospital
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name

Royal United Hospital Bath 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