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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 04/06/2015	**Condition category** Surgery	

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
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Royal United Hospital Bath NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration