

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/06/2015	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised controlled trial

Primary study design

Interventional

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes