ISRCTN33777350 https://doi.org/10.1186/ISRCTN33777350

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

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| **Submission date**<br>30/09/2005 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/09/2005 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>04/06/2015 | **Condition category**<br>Surgery | [_] Individual participant data<br>[_] 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
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London
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SW1A 2NL
+44 (0)20 7307 2622
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**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