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Trial to compare the Laryngeal Tube Sonda® with the ProSeal® Laryngeal Mask Airway

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 06/03/2009	**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
N0212120671

Study information

Scientific Title

Study objectives
Does the Laryngeal Tube Sonda® perform as well as the ProSeal® Laryngeal Mask Airway?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local research ethics committee approved the study

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
ProSeal® Laryngeal Mask Airway versus Laryngeal Tube Sonda®

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Added 06/03/2009:
Airway seal pressure

Key secondary outcome(s)
Added 06/03/2009:
1. Insertion success and time
2. Manipulations required
3. Ventilation quality
4. Peak and plateau airway pressures
5. Ability to pass a gastric tube
6. Fibre-optic laryngeal view

Completion date
01/06/2003

Eligibility

Key inclusion criteria
Added 06/03/2009:
1. American Society of Anaesthesiology (ASA) grade I - III
2. Undergoing elective surgery in the supine or lithotomy position
3. Use of neuromuscular blockade and LMA is appropriate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Added 06/03/2009:
1. Any pathology of the neck, upper respiratory tract or upper alimentary tract
2. At increased risk of pulmonary aspiration of gastric contents
3. Weighed less than 50 kg or had a height less than 155 cm

Date of first enrolment
01/03/2003

Date of final enrolment
01/06/2003

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Anaesthetics
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
Department of Health (UK)

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?
Results article	results	01/08/2005		Yes	No