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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

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 measure
Added 06/03/2009:
Airway seal pressure

Secondary outcome measures
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

Overall study start date
01/03/2003

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Added 06/03/2009: 32 patients

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
England

United Kingdom

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

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2005		Yes	No