

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

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/03/2009	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr T Cook

Contact details
Department of Anaesthetics
Royal United Hospital
Bath & North East Somerset Council
Bath
United Kingdom
BA1 3NG

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