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

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

## 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

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

## Study design

Randomised controlled trial

#### Primary study design

Interventional

#### 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