# Trial to compare the laryngeal mask airway (LMA) Unique™ with the Softseal™ LMA for airway management

	Prospectively registered	
Stopped	☐ Protocol	
Overall study status	Statistical analysis plan	
Stopped  Condition category	[X] Results	
	Individual participant data	
Surgery	Record updated in last year	
	Stopped  Condition category	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

## Type(s)

Scientific

#### Contact name

Dr Tim Cook

#### Contact details

Anaesthesia Royal United Hospital Bath & North East Somerset Council Bath United Kingdom BA1 3NG

# Additional identifiers

Protocol serial number N0212123055

# Study information

Scientific Title

#### **Study objectives**

Does one of these new single use laryngeal mask airways (LMAs) offer a clinically important benefit over the other?

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

## Study design

Randomised controlled trial

#### Primary study design

Interventional

## Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Surgery: Anaesthesia

#### **Interventions**

LMA Unique™ versus Softseal™ LMA

## Intervention Type

Procedure/Surgery

#### Phase

Not Applicable

#### Primary outcome(s)

Success of airway placement

## Key secondary outcome(s))

- 1. Manipulations and complications during use
- 2. Ease of insertion
- 3. Airway and fibre-optic assessment of airway positioning
- 4. Complications post-operatively

#### Completion date

30/09/2004

## Reason abandoned (if study stopped)

We planned to study 300 patients but interim analysis demonstrated the study should be stopped after 100 patients.

# **Eligibility**

# Key inclusion criteria

- 1. Patients undergoing elective anaesthetic/surgery
- 2. Did not receive neuromuscular blockade

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

**Not Specified** 

#### Sex

**Not Specified** 

## Key exclusion criteria

Does not meet inclusion criteria

#### Date of first enrolment

01/05/2003

#### Date of final enrolment

30/09/2004

# Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre

Anaesthesia

Bath United Kingdom BA1 3NG

# Sponsor information

## Organisation

Department of Health

# 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	01/12/2005		Yes	No