

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

Submission date 30/09/2005	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan ☒ Results
Last Edited 06/03/2009	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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