

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

Submission date 30/09/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Stopped	<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 <input type="checkbox"/> 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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Bath
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

LMA Unique™ versus Softseal™ LMA

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Success of airway placement

Secondary outcome measures

1. Manipulations and complications during use
2. Ease of insertion

3. Airway and fibre-optic assessment of airway positioning
4. Complications post-operatively

Overall study start date

01/05/2003

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

300 patients planned, study stopped after 100 patients.

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

England

United Kingdom

Study participating centre

Anaesthesia
Bath
United Kingdom
BA1 3NG

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

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	01/12/2005		Yes	No