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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 [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2005	**Overall study status** Stopped	
Last Edited 06/03/2009	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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