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A prospective randomised comparison of I-gel and LMA-unique Supraglottic Airway Devices for use during Clinical Anaesthesia

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 28/10/2009	**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

N0176179733

Study information

Scientific Title

Study objectives
The rate of successful insertion during routine clinical anaesthesia is the primary outcome measure for comparison between the two supraglottic airway devices. 'Successful insertion' is defined as the provision of both an unobstructed, patient airway as judged clinically and by the measurement of satisfactory leak pressure. Pressure is needed to ventilate the lungs. Above a certain normal pressure, there is an audible leak of gas from between the patient's larynx and the airway management device. This leak pressure is recorded routinely all anaesthetics. The better the seal of a device at the patient's larynx, the higher the leak pressure.

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
1. Selection of research participants
2. Explanation of research proposal and procedure, including provision of written information sheet and sufficient time for questions
3. Written consent
4. Randomisation to receive either i-gel airway (I-gel group) or LMAu (LMA group)
5. Induction and maintenance of anesthesia in a standard manner
6. Insertion of selected airway device, examining study objectives (as above)

7. After successful insertion, it will be left in place for the maintenance of anaesthesia
8. After the end of the operation the patient will regain consciousness and the device will be removed
9. Routine assessment will be made of sore throat etc, as is normal practice

Intervention Type
Device

Phase
Not Specified

Primary outcome measure
Clinically successful placement of the device, ie 'successful insertion' and 'adequate leak pressure'.

Secondary outcome measures
Incidence of complications and post-operative presence of any subjective difficulty or pain with speaking, swallowing, jaw or neck movement, or any alteration to hearing or tongue sensation.

Overall study start date
18/05/2006

Completion date
18/05/2008

Eligibility

Key inclusion criteria
1. ASA I or II patients (fit and healthy or with minor well-controlled chronic disease)
2. Age 16-70 years
3. Weight 30-120 kg
4. Not pregnant
5. Booked for elective surgery of duration <2 hours
6. Fasted
7. Normal airway assessment
8. Consenting

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
300 patients

Key exclusion criteria

1. Age <16 or >80, or weight <30 or >120kg
2. Pregnancy
3. Emergency surgery
4. Surgery > 2 hours duration
5. Patient not fit (ASA >=III)
6. Patient not starved
7. History of symptomatic reflux disease
8. History of difficult airway mgmt during previous anaesthesia
9. Anticipated difficult airway
10. Previous radiotherapy to head/neck
11. Heavy smokers >20 cigarettes/d
12. Non-consenting

Date of first enrolment
18/05/2006

Date of final enrolment
18/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Anaesthetics Department
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
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SW1A 2NL
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Sponsor type

Government

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

Funder(s)

Funder type
Government

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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	01/12/2009		Yes	No