

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/10/2009	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

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, patent 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 anaesthesia 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

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

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