ISRCTN57834329 https://doi.org/10.1186/ISRCTN57834329

Ease of placement of the laryngeal tube during manual-in-line neck stabilisation.

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 21/07/2009	**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
N0176140630

Study information

Scientific Title

Study objectives
The laryngeal Tube (LT) is used in anaesthetics to secure patients' breathing and to administer oxygen and anaesthetic gases. LT consists of an airway tube with a small cuff attached at the tip (distal cuff) and a larger cuff at the middle part of the tube (proximal cuff). LT is inserted through the mouth. The proximal cuff provides a seal by forming a plug just above the voice box (larynx) and the distal cuff seals the gullet (oesophagus) inlet. There is a hole in the tube between the two cuffs to supply oxygen and anaesthetic gases through it. LT has a role in the airway management during anaesthesia and cardiopulmonary resuscitation. In patients with injury to the neck ("unstable necks"), airway management may be required while the head and neck are stabilised with the anaesthetist' assistant holding them in neutral position ("manual in-line sabilisation"). It is possible that this may make placement of the device more difficult. We wish to determine if the manual in-line stabilisation of the head and neck would alter the ease of insertion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled crossover trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Anaesthesia

Interventions
Randomised controlled trial. Comparison of 2 different insertion positions

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Clinically assessed adequacy of the ventilation via LT inserted in two different positions.

Secondary outcome measures
Ease and time of insertion of LT

Overall study start date
01/05/2003

Completion date
30/04/2004

Eligibility

Key inclusion criteria
55 patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/05/2003

Date of final enrolment
30/04/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthetics
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
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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
Hospital/treatment centre

Funder Name
Oxford Radcliffe Hospitals NHS Trust (UK)

Funder Name
Not available

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	01/12/2004		Yes	No