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Effect of laryngeal mask airway (LMA) in small airway function in the postoperative period compared with the endotracheal tube (ETT)

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/04/2018	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

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

N0226190719

Study information

Scientific Title
Effect of laryngeal mask airway (LMA) in small airway function in the postoperative period compared with the endotracheal tube (ETT)

Study objectives
To compare the effect of laryngeal mask airway versus end tracheal tube on small airway function in the post operative period.

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Small airway function

Interventions
Patients will be randomised to either LMA or ET for anaesthesia.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure

Changes in airway resistance in the lung.

Secondary outcome measures
If there are marked differences it will add a new dimension to the choice of airway device used in patients with constrictive/obstructive airways disease.

Overall study start date
05/02/2007

Completion date
05/02/2009

Eligibility

Key inclusion criteria
1. ASA Grades 1 or 2 (ie healthy patients of patients with well controlled chronic conditions) for elective surgery expected to last >30mins, on peripheral or body surfaces. We expect this would mean mainly orthopaedic or plastic surgery patients but could include vascular (varicose veins)
2. Smokers and non-smokers
3. BMI <30
4. Patients consenting to the research
5. No history of gastric reflux

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
80 participants; 2 groups of 40. 40 patients recruited as of August 2008.

Key exclusion criteria
1. ASA 3 or higher
2. BMI >30
3. Patients suffering with gastro-oesophageal reflux
4. Patients unable to consent to the research or those who refuse to participate

Date of first enrolment
05/02/2007

Date of final enrolment
05/02/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University Hospital of South Manchester NHS Foundation Trust
Manchester
United Kingdom
M23 9LT

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
+44 (0)20 7307 2622
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
University Hospital of South Manchester NHS Foundation Trust (UK), 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