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Comparison of two airway devices to aid breathing during percutaneous tracheostomy

Submission date 09/11/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/11/2009	**Overall study status** Completed	
Last Edited 12/06/2015	**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
09/MRE00/54

Study information

Scientific Title
A prospective randomised controlled trial of airway management in patients undergoing percutaneous tracheostomy and its effect on hypercarbia

Study objectives
Maintenance of the airway during percutaneous tracheostomy with the laryngeal mask airway (LMA) Supreme™ supraglottic airway device, is at least as effective at maintaining mechanical ventilation as the use of a cuffed endotracheal tube.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, 13/08/2009

Study design
Prospective 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
Percutaneous tracheostomy

Interventions
LMA Supreme™ versus cuffed oral endotracheal tube. Duration of intervention is variable but no more than 60 minutes. There is no follow up beyond the procedure itself.

Intervention Type
Procedure/Surgery

Primary outcome measure
Change in partial pressure of carbon dioxide in arterial blood (PaCO2) levels between start of percutaneous tracheostomy procedure and completion of tracheostomy procedure.

Secondary outcome measures
Measured during the procedure and immediately on completion of the procedure:
1. Combined complications (desaturation less than 92% during procedure, repositioning of airway device during procedure, loss of airway during procedure)
2. How many people required to help with airway maintenance
3. View on bronchoscopy of procedure
4. Time to airway ready
5. Total time from incision to tracheostomy placement

Overall study start date
01/12/2009

Completion date
01/12/2011

Eligibility

Key inclusion criteria
1. Aged over 18 years, either sex
2. Require a percutaneous tracheostomy as part of ongoing intensive care therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Aged less than 18 years
2. Patient or relative/welfare guardian refusal
3. Treating clinician refusal

Date of first enrolment
01/12/2009

Date of final enrolment
02/09/2011

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre
St John's Hospital
Livingston
United Kingdom
EH54 6PP

Sponsor information

Organisation
NHS Lothian (UK)

Sponsor details
c/o Dr Tina McClelland
R&D Governance Manager
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United Kingdom
EH16 4TJ

Sponsor type
Government

Website
http://www.nhslothian.scot.nhs.uk/

ROR
https://ror.org/03q82t418

Funder(s)

Funder type
Government

Funder Name
NHS Lothian (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	01/07/2014		Yes	No