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Assessment of intraoperative microaspiration

Submission date 18/07/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 11/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 04/05/2017	**Condition category** Surgery	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Postoperative pulmonary infections (lung infections) lead to significant morbidity (illness) and mortality (death), burdening healthcare cost, even though risk can be more accurately determined. A major cause of pulmonary infections is atelectasis which is the collapse of the lung due to a lack of gas. Intubation is when a plastic tube is placed into the windpipe to help keep the airway open using an endotracheal tube (ETT). Although a lot of effort has gone into correcting it, microaspiration (fluid in the lungs) of contaminated upper airway secretions due to an inadequately sealed ETT is still a major cause of post-intubation pneumonia. The design of the ETT has been improved, using different materials and shapes in order to provide a better seal. The aim of this study is to see how much microaspiration occurs using a dye solution in intubated patients in a short term time frame during lumbar surgery when comparing different types of ETT.

Who can participate?
Adults between the ages of 18 to 74 who are undergoing lumbar surgery.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive the traditional round cuff made of PVC. Those in the second group receive a tapered shaped polyurethane (PU) cuff and the last group receives a tapered shape PVC cuff. Participants are assessed for their levels of microaspiration (through the dye) at ten minutes, 30 minutes, 60 minute and 120 minutes after the surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Brussels (Belgium)

When is the study starting and how long is it expected to run for?
October 2008 to May 2011

Who is funding the study?
University Hospital Brussels (Belgium)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2008/210

Study information

Scientific Title
Comparative study between a cylindrical cuffed endotracheal tube, a polyurethane tapered shaped cuffed and a PVC tapered shaped cuffed endotracheal tube with respect to intraoperative microaspiration

Study objectives
We hypothesized that both shape and material have a beneficial influence on microaspiration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MEC UZ Brussel approved on 20/11/2008, ref: 2008/210

Study design
Single center randomized interventional study

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
Lumbar surgery

Interventions
We aim for 22-24 patients/group, the groups differ from each other by the cuff used: group 1 traditional cylindrical PVC cuff, group 2 tapered shape polyurethane (PU) cuff and group 3 tapered shape PVC cuff.

Microaspiration is assessed with methylthioninium chloride at 10min, 30min, 60min, 120min after intubation if the surgical procedure lasted so long.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Microaspiration as assessed with methylthioninium chloride. We introduced Methylthioninium chloride as dye solution to demonstrate potential aspiration of oropharyngeal secretions along the endotracheal cuff. By means of bronchoscopy we checked the descent of the dye solution.

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/10/2008

Completion date
31/05/2011

Eligibility

Key inclusion criteria

1. Patients sheduled for lumbar surgery
2. Age >17 years and < 75 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
75

Key exclusion criteria
Comprised narrowed laryngeal or tracheal lumen with the inability of intubation

Date of first enrolment
15/10/2008

Date of final enrolment
31/05/2011

Locations

Countries of recruitment
Belgium

Study participating centre
Laarbeeklaan 101
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Sponsor information

Organisation
University Hospital Brussels (Belgium)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/038f7y939

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Brussels (Belgium)

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