

# Assessment of intraoperative microaspiration

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<b>Registration date</b> 11/08/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/05/2017	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?  
Dr Jan Poelaert  
jan.poelaert@uzbrussel.be

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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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 scheduled 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

Jette

Belgium

1090

## Sponsor information

**Organisation**

University Hospital Brussels (Belgium)

**Sponsor details**

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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