

# Flexible nasopharyngoscopy to assess the dislocation rate of airway exchange catheters in the post-operative-care-unit (PACU)

<b>Submission date</b> 07/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/04/2019	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Marius Wipfli

**Contact details**  
University Hospital Bern  
Freiburgstrasse  
Bern  
Switzerland  
3010

## Additional identifiers

## Study information

**Scientific Title**  
Flexible nasopharyngoscopy to assess the dislocation rate of airway exchange catheters in the post-operative-care-unit (PACU): a prospective observational study

**Study objectives**  
After insertion of an airway exchange catheter through an endo-tracheal tube and extubation of that tube over the airway exchange catheter in the operating room (OR), the incorrect

placement (dislocation rate) of an orally placed airway exchange catheter is significantly higher than of a nasally placed airway exchange catheter from the time of admission in the post-operative-care-unit (PACU) until remove of the airway exchange catheter. The difference in dislocation rates is at least 10%.

Null hypothesis:

There is no significant difference between oral and nasal airway exchange catheter regarding correct endo-tracheal placement after extubation until removal.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Local ethics committee (Kantonale Ethikkommission KEK) approved on the 20th April 2010 (ref: 060/10)

### **Study design**

Prospective observational study, non-randomised, non-controlled

### **Primary study design**

Observational

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Anaesthesia

### **Interventions**

After extubation in the OR on admission to the PACU we will assess the position of the CAEC with a small flexible pharyngoscope of a diameter of only 2.8 mm (EF-BNI, Acutronic Medical Systems AG, Switzerland). We will assess the position in both groups (oral and nasal) and at three different times: On admission of the patient to the PACU, at removal of the CAEC (in most cases at the end of the PACU-stay) and at any change of ETCO<sub>2</sub> waveform indicating no gas flow. This painless examination is a standard investigation during an ENT exploration at the ENT Department of the University Hospital and may be done without further sedation or analgesics.

### **Intervention Type**

Procedure/Surgery

### **Phase**

Not Applicable

### **Primary outcome(s)**

Dislocation rates of nasally placed airway exchange catheters versus dislocation rates of orally placed airway exchange catheters. Definition of dislocation is visualised extra-tracheal position (oesophageal, pharyngeal, enoral) of the CAEC (flexible nasopharyngoscopy).

### **Key secondary outcome(s)**

1. Demographic and morphometric data of the patients
2. Type of surgery

3. Duration of surgery and anesthesia
4. Blood loss during surgery
5. Indication for the airway exchange catheter
6. Duration of use of airway exchange catheter in minutes (mean, SD)
7. Number of events of ETCO<sub>2</sub> measurement (indicating no gas flow)
8. Position of the CAEC at the time of an event of ETCO<sub>2</sub> assessed by flexible nasopharyngoscopy
9. Sensitivity and specificity of ETCO<sub>2</sub> measurement over CAEC
10. Patients tolerance against airway exchange catheter orally versus nasally (category 1, tolerated with any problem "C 10 not tolerated at all, therefore CAEC removed)
11. Indication for the removal of the airway exchange catheter
12. Duration of use of airway exchange catheter in minutes (mean, SD)
13. Re-intubation rate and time after extubation in minutes

**Completion date**

31/12/2011

## Eligibility

**Key inclusion criteria**

All patients (aged greater than 18 years, either sex) entering the PACU with an oral or nasal airway exchange catheter will be included in the observational study. After they regained full consciousness, they will be asked whether the obtained data may be used for publication (informed consent).

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

182

**Key exclusion criteria**

1. Refusal of post-intervention written informed consent
2. Aged less than 18 years

**Date of first enrolment**

01/06/2010

**Date of final enrolment**

31/12/2011

## Locations

**Countries of recruitment**

Switzerland

**Study participating centre****University Hospital Bern**

Bern

Switzerland

3010

## Sponsor information

**Organisation**

Inselspital, University Hospital Berne (Switzerland)

**ROR**

<https://ror.org/01q9sj412>

## Funder(s)

**Funder type**

University/education

**Funder Name**

University of Berne (Switzerland) - Scientific fund of the Department of Anaesthesia and Pain Therapy and scientific fund of the Swiss Society of Anesthesiologists (SGAR)

## Results and Publications

**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?
<a href="#">Results article</a>	results	11/04/2019	12/04/2019	Yes	No