

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

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

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
N/A

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

Secondary study design

Cohort study

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

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 ETCO₂ 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 measure

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).

Secondary outcome measures

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 ETCO₂ measurement (indicating no gas flow)
8. Position of the CAEC at the time of an event of ETCO₂ assessed by flexible nasopharyngoscopy
9. Sensitivity and specificity of ETCO₂ 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

Overall study start date

01/06/2010

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

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)

Sponsor details

Scientific fund of the Department of Anesthesia and Pain Therapy

Freiburgstrasse

Bern

Switzerland
3010

Sponsor type
University/education

Website
<http://www.insel.ch/>

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

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	11/04/2019	12/04/2019	Yes	No