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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

Registration date
10/06/2010

Overall study status
Completed

Last Edited
12/04/2019

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 disloction 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)

Primary study design
Observational

Study design
Prospective observational study, non-randomised, non-controlled

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 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(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 nasopharyngosopy).

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 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

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?
Results article	results	11/04/2019	12/04/2019	Yes	No