The Integrated Pulmonary Index (IPI) for assessment of the postoperative respiratory condition

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28414

Source
Nationaal Trial Register

Brief title
IPI study

Health condition

Postoperative condition
Respiration
Monitoring

Postoperatieve conditie
Ademhaling
Monitoring

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: Covidien

Intervention

Outcome measures

Primary outcome

The function of the IPI monitor and the number of IPI-events during the first day and night after after anesthesia and the use of opiods (ie. number of IPI events, IPI AUC) are the main end-points.

Secondary outcome

The secondary end-point is to get information to start another IPI-study in which the difference between the current protocol will be compared to treatment of respiratory problems using the IPI.

Additional data that is collected and may serve as covariate in the data analysis includes:

„PjnPatient related parameters:

Sex; Weight; Age; BMI; Underlying disease; Comorbidity; Medication; OSAS (STOP bang criteria).

„PjnAnesthesia related parameters:

Anesthesia type (inhalational versus intravenous); use of NMB agent; use of reversal agent (neostigmine or sugammadex); ketamine use during anesthesia; use of epidural, spinal or local block; opioid type and dose.

„PjnPain treatment (incl. dose):

Epidural or local anesthesia/analgesia; PCA morphine; Ketamine use; Oral opioids (oxycodone); SC opioid use (morphine).

„PjnSurgery related parameters:

Surgery type; Duration of surgery; Blood loss.

„PjnPost-op location:

Ward-recovery-PACU-ICU

Study description

Background summary

In 40 patients following elective surgery under general anesthesia that require opioid pain relief the IPI will be measured at the PACU (post anesthesia care unit) during the first postoperative night (end of study 8 AM 1st postoperative day). In these 40 patients the IPI will be measured but no action will be undertaken based on the IPI. Local protocol will be followed in which nurses base their decision to intervene (ie. stimulate the patient, call for help) on sedation level and respiratory rate. The study will generate data on the incidence of respiratory events in the study population to be potential used in a next IPI-study where the focus is on interventions as a result of the IPI.

Study objective

The main goal of the study is to assess the incidence of respiratory events using the IPI device.

Study design

The observation will start from the arrival of the patient on the PACU untill 8 am on the first postoperative day

Intervention

Postoperative respiratoir condition

Contacts

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Eligibility criteria

Inclusion criteria

Adult (> 17 years) ASA 1-3 patients that underwent elective surgery under general anesthesia who require opioid pain relief and are able to wear or retain the IPI device post-operatively.

Exclusion criteria

Patients having ENT, facial or neurological/ brain (head) surgery or are not able to give informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-09-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5231
NTR-old	NTR5455
Other	METC LUMC : P15.170

Study results