An observational study measuring respiratory rate as assessed by respiR8® in post operative patients aged 60 years and above

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Primary objective • To estimate the frequency of subjects with at least one apnoeic episode, defined as respiratory rate

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON40777

Source
ToetsingOnline

Brief title
RespiR8-2 study

Condition

- Other condition

Synonym
postoperative breathing monitoring

Health condition

postoperatieve monitoring

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Anaxsys Technology Ltd

Intervention

Keyword: apneas, breathing, postoperative, respiratory frequency

Outcome measures

Primary outcome

Breathing frequency

Secondary outcome

Oxygen saturation

Study description

Background summary

Background
Clinically significant respiratory depression post-operatively remains a serious patient safety risk and respiratory rate is one vital sign that gives an early indication of patient deterioration. However, respiratory rate is often not measured continuously and it is difficult to measure accurately. It is recognised that intermittent spot checks are not adequate for reliably recognising clinically significant respiratory changes in the postoperative period. , Continuous quality improvement in electronic monitoring is sought based on an increased likely risk to miss respiratory depression in patients. This monitoring would benefit from being from a central location, with information being reliably transmitted to the healthcare professional minimising the failure of caregivers to recognise respiratory depression. Current clinical practice for measurement of respiratory rate in post-operative recovery is predominantly a manual method with Healthcare Professionals (HCPs) periodically counting chest excursions. Respiratory rate can be recorded from ECG monitor detection of chest excursions. Chest excursion counts can, however, be misleading as these counts may indicate respiratory rate but do not confirm gas movement into and out of the lungs as in the instance of an upper airway obstruction, thus not detecting obstructive apnoeas.
The experience from the use of respiR8® in post-operative recovery has shown that respiratory rate often falls below 6 breaths per minute and periods of

apnoea are detected. Falls in respiratory rate to 6 breaths per minute or below have been noted when patients are sleeping and respiratory depression alarms have alerted nurses as much as 2 hours earlier than oxygen saturation alarms.
Respiratory depression measured by episodes of desaturation versus incidence of bradypnoea demonstrates 41% patients having bradypnoea and only 12% patients displaying a desaturation event. This further supports the view that pulse oximetry may be a late indicator of hypoventilation.
Oxygen saturation levels as measured by pulse oximetry do fall to below 95% in spite of the patient being given supplemental oxygen. Pulse oximetry is frequently used in post-operative care as a means of measuring for adequate ventilation but is not a replacement for respiratory rate measurement being a late sign of clinical deterioration. , When supplemental oxygen is administered blood oxygen saturation levels are slow to respond, even when the patient ceases breathing. In this instance an automated, non-intrusive respiratory rate counter such as the respiR8® could provide valuable support to health care staff.

Rationale for this study
Monitoring systems can both detect and predict patient deterioration. Predictive systems do not require continuous data collection for patients to be selected for higher levels of care.i The primary function of detective systems is to identify and report deterioration. For this study the respiR8® will generate continuous visual data and not continuous automated print out data. Irregular breathing patterns as signatures of clinical changes occurring will alert that a patient is becoming apnoeic and will enable an intervention and safety net to be available where it might have otherwise been missed.

Respiratory rate, normally described in breaths per minute is between 12 and 18 breaths per minute for a normal adult. Nurse awareness of eupnoea (normal rate and depth), bradypnoea (abnormally slow respiration), tachypnoea (abnormally fast respirations) and apnoea (cessation or absence of breathing) is essential for post-operative patient care.

This study is a precursor to investigating correlations between respiratory complications and cognitive dysfunction in o¬¬¬¬¬lder patients. In the older population, duration of anaesthesia and respiratory complications are risk factors for post-operative delirium and early cognitive dysfunction , In 1200 patients of more than 60 years of age an incidence of post-operative cognitive dysfunction (POCD) of ~25% at 1 week and 10% at 3 months post-operatively and ~1% up to 2 years after the operation . There is significant association between increasing POCD and respiratory complications, therefore attention is needed to minimise and avoid respiratory complications where possible.
The respiR8® monitors patients within the post-operative setting and could be used as a system for continuous, automated monitoring of patients ensuring that any excursion into an abnormal respiration rate is able to be detected and acted upon by medical staff.

The respiR8® is approved for sale in Europe (CE marked).

Study objective

Primary objective
• To estimate the frequency of subjects with at least one apnoeic episode, defined as respiratory rate <=6, detected using the respiR8® device for up to 6 hours after surgery. Apnoea is defined as 10 seconds of no breathing activity or a respiratory rate <=6 of undefined duration.

Secondary objectives
The secondary objectives are:
• To estimate the frequency of subjects with multiple apnoeic episodes detected using the respiR8® device. Episodes of apnoea will be separated by episodes of non-apnoeic breathing.
• To estimate frequency of respiratory rate abnormalities. Tachypnoea (>=18 breaths per minute for at least 20 seconds) and bradypnoea (<= 10 breaths per minute for at least 20 seconds).
• To estimate the level of association between the respiratory rate from the respiR8® device and oxygen saturation levels.
• To study the distribution of respiR8® respiratory rate values over time.
• To study the distribution of saturation of peripheral oxygen SpO2 levels over time.
• To study episodes of oxygen desaturation of <=94%.
• To investigate frequency of actions and interventions taken by clinical staff, frequency of the respiR8® mask being removed from patients face with reasons.

Study design

Observational and open

Study burden and risks

The burden to the patient is minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Males and females having elective surgery
• Having surgery requiring anaesthesia for at least 60 minutes
• Aged >= 60 years
• Expected to stay in hospital for at least 12 hours
• General Anaesthesia / regional anaesthesia
• Able to read and understand the English or Dutch Patient Information Leaflet and Consent Form.

Exclusion criteria

• Head, neck and facial surgery
• Inability to wear or retain a standard oxygen mask post-operatively
• Emergency (non-elective) surgery

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-09-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2014
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL48616.058.14