Postoperative monitoring of respiratory function

No registrations found.

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

Summary

ID

NL-OMON28102

Source
NTR

Brief title
PulMONIC

Health condition

(acoustic) respiratory rate (RRa), heart rate (HR), saturation, pulse oximetry
(akoestische) ademhalingsfrequentie, hartslag, saturatie

Sponsors and support

Primary sponsor: Vrije Universiteit medical center (VUmc)
Source(s) of monetary or material Support: Masimo Corporation

Intervention

Outcome measures

Primary outcome

• Number of hypoxemic events (SpO2<92%) in the postoperative setting on day 1-4 following surgery

• Number of episodes of aberrant respiratory rates (RR ≤9 brpm or RR ≥15 brpm and RR ≥21

brpm) according to the the MEWS criteria (see attachment)

Secondary outcome

• Suspected pulmonary infection (Treatment with antibiotics for a respiratory infection, plus at least one of the following criteria: New or changed sputum, New or changed lung opacities on a clinically indicated chest radiograph, temperature >38.3°C, leukocyte count >12,000/mm3, pleural effusion or chest radiograph demonstrating blunting of the costophrenic angle, loss of the sharp silhouette of the ipsilateral hemidiaphragm.

• Atelectasis (Suggested by lung opacification with shift of the mediastinum, hilum, or hemidiaphragm toward the affected area, and compensatory overinflation in the adjacent nonatelectatic lung).

• Pneumothorax (Air in the pleural space with no vascular bed surrounding the visceral pleura) Bronchospasm Newly detected expiratory wheezing treated with bronchodilators.

• Postoperative pain (visual analogue scale of 4 or higher)

• Fever (body temperature of 38C or higher)

• General infection requiring antibiotics use

• Device failure

Study description

Background summary

In this pilot study we aim to evaluate the number of patients that develop respiratory dysfunction in the postoperative period, and whether respiratory dysfunction can be related to the development of postoperative complications.

Study objective

In this pilot study we aim to determine the course of vital patient parameters in the postoperative period using Masimo remote monitoring, in particular the incidence and severity of postoperative hypoxemia and changes in respiratory rate.

Our hypothesis is that the incidence of hypoxemia or a respiratory rate ≤9 breaths per minute (brpm) or RR ≥15 brpm and RR ≥21 brpm above 20 breaths per minute in the postoperative period is significant in patients admitted to a general surgical ward, and adequate monitoring may prevent deterioration of the health condition of these patients as it allows early interventions.

Study design

Postoperative patients will be monitored for four days. Pulse oximetry and heart rate data will be converted to a per minute value. The respiratory rate date will be converted to a per 30 second value to be able accurately register respiratory depression or respiratory failure.

Intervention

Postoperative patients after gastro-intestinal surgery (esophagus-, liver- and pancreas surgery) will be monitored the first 4 post-operative days on the surgical ward. Patient vital parameters, heart rate, pulse oxymetry, acoustic respiratory rate will be monitored by a remote wireless monitor, Radius 7 (Masimo) worn on an arm that is connected to an adhesive sensor in the patients' neck and a probe on the index finger. Data is collected , downloaded and securely stored with a direct cable connection to the root on a daily basis. The data are collected on the root with a secured Bluetooth connection with the remote monitor. These data will be compared with the data that are retrieved from the electronic medical patient file.

Contacts

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Eligibility criteria

Inclusion criteria

Postoperative patients after upper abdominal surgery (eg esophagus-, liver- and pancreas surgery), >18 years old, speaking Dutch or English, with a preoperative determined moderate or high risk of development of postoperative pulmonary complications based on the ARISCAT score of 26 or higher.

Exclusion criteria

<18 years old, not speaking Dutch or English, ARISCAT score < 26

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-01-2016
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2016
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	NL5522
NTR-old	NTR5650
Other	METc VU medisch centrum : 2015/496

Study results