Postoperative monitoring of respiratory function

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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…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28102

Bron
NTR

Verkorte titel
PulMONIC

Aandoening

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

Ondersteuning

Primaire sponsor: Vrije Universiteit medical center (VUmc)
Overige ondersteuning: Masimo Corporation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	25-01-2016
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-01-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5522
NTR-old	NTR5650
Ander register	METc VU medisch centrum : 2015/496

Resultaten