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Continuous remote monitoring to detect critical early warning scores in patients after abdominal surgery

Submission date
07/05/2019

Recruitment status
No longer recruiting

Registration date
01/10/2019

Overall study status
Completed

Last Edited
07/09/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
To evaluate patients in the postoperative period following abdominal surgery, especially the incidence of hypoxemia (low level of oxygen in the blood), changes in respiratory rate and incidence of critical early warning scores.

Who can participate?
Adult patients who underwent major abdominal surgery with an increased preoperative risk for postoperative pulmonary complications can participate in the study

What does the study involve?
Heart rate, respiratory rate, pulse oximetry data collected from the remote monitoring device. Available heart rate, blood pressure, respiratory rate, temperature, pulse oximetry data measured by the nurses will be retrieved from hospital records. Patient vital parameters, heart rate, pulse oximetry, the respiratory rate will be monitored by a remote wireless monitor, worn on an arm, the size of a small i-pod, that is connected to an adhesive sensor in the patients' neck and a probe on the index finger. Data is collected through WiFi or Bluetooth to a distant monitor

What are the possible benefits and risks of participating?
If an acute detoriation might occur the remote monitoring data will be made available for the medical team to support medical decision making.
There are no negative effects for patients volunteering in the study.

Where is the study run from?
VU University Medical Center Amsterdam, Netherlands

When is the study starting and how long is it expected to run for?
February 2016 to December 2016

Who is funding the study?
VU University Medical Center Amsterdam, Netherlands

Who is the main contact?
Mr Hugo Touw,
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Contact information

Type(s)
Public

Contact name
Mr Hugo Touw

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2015.496

Study information

Scientific Title
Continuous remote monitoring to detect critical early warning scores in patients after abdominal surgery: a prospective observational study

Acronym
PulMONIC

Study objectives
Critical modified early warning score (MEWS) is detected with continuously remote monitoring of vital signs in patients after abdominal surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2016, Human Subjects Committee of VUmc (Medisch Ethische Toetsingscommissie
VU medisch centrum, voorzitter: prof. dr. JA Rauwerda, intern postadres: BS7, kamer H-565; 020-44 45585; metc@vumc.nl)

Study design
Prospective explorative observational feasibility study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Postoperative care

Interventions
Patients are asked to wear the remote monitoring device for clinical evaluation for the first 3 days after the operation. During the pilot, no alarms will be set on the device. Treatment and monitoring will be according to daily practice. Volunteering in the pilot study will not influence their treatment. There will be a short questionnaire (5 min) after 3 days of wearing the remote monitor. Patients can decide to discontinue wearing the monitor at all times.

Heart rate, respiratory rate, pulse oximetry data collected from the remote monitoring device. Available heart rate, blood pressure, respiratory rate, temperature, pulse oximetry data measured by the nurses will be retrieved from hospital records. Patient vital parameters, heart rate, pulse oximetry, the respiratory rate will be monitored by a remote wireless monitor, worn on an arm, the size of a small i-pod, that is connected to an adhesive sensor in the patients' neck and a probe on the index finger. Data is collected through WiFi or Bluetooth to a distant monitor. Patient records are checked for postoperative complications in 30 days.

Intervention Type
Procedure/Surgery

Primary outcome measure
Critical early warning scores measured by continuous remote monitoring of the respiratory rate, SpO2 and pulse rate in four postoperative days.

Secondary outcome measures
Postoperative pulmonary complications retrospectively scored using patient records.

Overall study start date
01/05/2015

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Adult patients who underwent major abdominal surgery with an increased preoperative risk for postoperative pulmonary complications

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Withdrawal of informed consent
2. Cancelled surgery
3. Total monitoring time < 8 hours

Date of first enrolment
01/02/2016

Date of final enrolment
27/12/2016

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center Amsterdam
Boelelaan 1115
Amsterdam

Netherlands
1081 HV

Sponsor information

Organisation
Vrije Universiteit Amsterdam (VUmc)

Sponsor details
Boelelaan 1115
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Sponsor type
University/education

Website
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ROR
https://ror.org/008xxew50

Funder(s)

Funder type
Not defined

Funder Name
Vrije Universiteit Amsterdam

Alternative Name(s)
VU University Amsterdam, VU University, VU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

2019 results in thesis https://research.vu.nl/ws/portalfiles/portal/82342764/cover.pdf

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	07/09/2021	Yes	No
Thesis results		04/07/2019	07/09/2021	No	No