

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

Submission date 07/05/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/09/2021	Condition category Surgery	<input type="checkbox"/> 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 deterioration 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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Netherlands
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Sponsor type

University/education

Website

www.vumc.nl

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