Surveillance of high-risk early postsurgical patients for real-time detection of complications using wireless monitoring

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

Summary

ID

NL-OMON49433

Source
ToetsingOnline

Brief title
SHEPHERD

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
complications after operation, Postoperative complications

Health condition

Post-operatieve patienten die een intermediar of hoog-risico ingreep ondergaan en-of trauma patienten

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Continuous wireless monitoring, Patient Outcome, Postsurgical ward, Vital signs

Outcome measures

Primary outcome

Disability-free survival 3 months after surgery (WHODAS 2.0, 12 items)

Secondary outcome

Parameters evaluated at 1 and 3 month after operation (questionnaires as wel

preoperatively):

• Disability (WHODAS 2.0, 12-item)

• EQ-5D-5L score

• SF-12 quality of life score (4 week retrospective scorecard)

• In-hospital Mortality, 30-day Mortality, 3-month Mortality

Parameters evaluated during the admission period:

• Patient characteristics (extent of surgery [minor/moderate/major],

urgent/elective surgery, duration of surgery, duration of recovery room stay

(PACU),)

• Length of hospital stay

• Discharge destination (other hospital, nursing home, rehabilitation facility,

home)

• Total number of complications per 100 patients, graded in severity according

to Dindo et al.(reference 12 research protocol) and grouped as

- Respiratory (e.g., Pneumonia)

- Cardiac (e.g., Arrhythmia, Congestive heart failure)

- Neurological (e.g., Delirium)

- Gastrointestinal (e.g., Anastomotic leakage or Ileus)

- Renal (e.g., acute kidney injury)

- Other (e.g., Wound dehiscence, Bleeding)

• Number of patients with one or more complications

- Comprehensive Complication Index 14

- Cost of treatment for complications

- Rate of unplanned ICU admissions

- ICU admission score (APACHE II15)

- ICU length of stay, ventilator free days, inotrope free days

- Rate of revision surgery

- Rate of false positive alarms

- Number of device failures (battery, signal loss)

- Rate of alarm responses, grouped according to action

- Heart rate variability over time, and as early marker of complications

- Quality of sleep

Study description

Background summary

Every year, approximately 1,500,000 surgical procedures are performed in The Netherlands. After major surgery, the complication rate is conservatively estimated at 25%, with a rate of 15% for major complications. In these patients, the most important problems are a failure to timely detect developing complications and a failure to adequately rescue those patients. Currently, measurement of vital signs and standardized assessment of patient wellbeing are routinely performed intermittently for every 8-12 hours, which may lead to a failure to detect of patients with complications.

Study objective

The aim of this study is to test the hypothesis that continuous wireless monitoring on the postsurgical ward will improve patient outcome, measured as disability-free survival at three months after surgery. Further, we hypothesize that this tight control regimen decreases length of hospital stay and treatment costs in patients with complications.

Study design

Interventional, step-wedge, prospective, clinical trial, participating wards will be included using a stepped-wedge design.

Study burden and risks

All patients, regardless of group allocation, will receive standardized perioperative care and assessment of vital functions, pain and wellbeing as is routine clinical patient care in the participating centres. The wards randomized to undergo continuous wireless monitoring will, in addition, receive the benefit of real-time monitoring and automated alerts when vital functions are deviating from baseline. There are no conceivable risks to taking part in this study, and treatment of complications is at the discretion of the responsible physician, and not influenced by this study. Therefore, the risk of study participation is very low.

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

Patients undergoing intermediate or high-risk major non-cardiac surgery at the Academic Medical Center Amsterdam (AMC), and the University Medical Center Utrecht (UMCU) or trauma patients

Exclusion criteria

Inability to give written and informed consent
Patient refusal.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-02-2018
Enrollment:	1892
Type:	Actual

Medical products/devices used

Generic name:	Sensium Vitals digital patch
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-11-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
ClinicalTrials.gov	NCT02957825
CCMO	NL59154.018.16