Mobile Vital Sign tracking in high risk surgical ward patients

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Primary objective:1. To investigate to what extent continuous vital sign monitoring can improve detection of adverse events in surgical ward patients as compared to current MEWS and nurse-worry assessmentSecondary objectives:2. To explore the…

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

Summary

ID

NL-OMON46115

Source
ToetsingOnline

Brief title
MoViSign

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
clinical deterioration, Pre and postoperative complications

Health condition

pre- en postoperatieve complicatie na hoog risico chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Pioneers in Health Care Voucher van Universiteit Twente & ZGT

Intervention

Keyword: Clinical deterioration, Early detection, Telemonitoring, Vital signs

Outcome measures

Primary outcome

The primary endpoint includes the time to detect adverse events. Adverse events of interest include pre- and postoperative complications with a Clavien Dindo class of II or higher, diagnosed according to standard guidelines.

A predefined Continuous Early warning score (CEWS) is used to assess presence of abnormalities in continuous vital signs where detection is defined as CEWS*3. Detection of complications by the MEWS method is defined as MEWS*3. Event detection by nurse observations is defined by annotation of nurse worry in the nurse checklists.

In patients where adverse events are diagnosed, the time to detect adverse events is calculated as the time difference between event identification and the moment that therapeutic actions targeting the event are started.

The time to detect adverse events of the CEWS is compared with 1) MEWS, 2) nurse observations, and 3) the combination of MEWS and nurse observations.

Secondary outcome

The quality and availability of vital sign data and robustness of the wireless connection is verified to investigate the technical feasibility of remote vital sign monitoring. The practical feasibility of mobile monitoring system and use

of the patient diary and nurse checklist for routine care is explored using the patient and nurse evaluations. This evaluation includes user comfort, user friendliness, time consumption, adherence, applicability, difficulty, and meaningfulness of the methods.

To explore potential decision support methods, we will investigate which vital sign patterns (i.e. absolute values, time trends and shapes) are related with adverse events using visual inspection and regression analysis. From this knowledge, various statistical models predicting adverse events serving will be tested as novel continuous warning score. To verify whether clinical context information improves detection of adverse events, the accelerometry data, patient symptoms and nurse worry indicators will be integrated in the prediction models.

Study description

Background summary

Patients admitted to the hospital for surgical care are at risk for developing adverse events in the pre- and postoperative trajectory. To identify clinical deterioration in surgical ward patients, the status of patients is monitored using routine nurse controls and the early warning score system (MEWS). However, current practice reveals that first signs of deterioration may remain unnoticed for hours or days while early intervention is critical to prevent secondary damage. This is of particular concern in patients undergoing upper gastrointestinal (GI) surgery or geriatric patients with traumatic hip fracture, which are known with high rates of complications developing during ward stay. To promote patient safety in wards, it might be interesting to use wireless sensor technologies that allow continuous vital sign tracking with minimal patient burden. These technologies can be integrated with decision support methods to assist medical professionals in the identification of deviant trends and abnormalities in vital signs.

Study objective

Primary objective:
1. To investigate to what extent continuous vital sign monitoring can improve detection of adverse events in surgical ward patients as compared to current MEWS and nurse-worry assessment

Secondary objectives:
2. To explore the feasibility of continuous mobile vital sign monitoring in surgical ward patients

3. To explore how automatic analytical methods and integration of clinical context information can support early identification of adverse events from vital signs

Study design

The prospective observational design includes patients admitted to the surgical ward for post- or perioperative care. Patients will receive standard ward care, including routine vital sign and MEWS measurements and observations by nurses. In addition to usual care, a selection of vital signs (heart rate, respiratory frequency, oxygen saturation, skin temperature) and accelerometry is continuously registered using wireless mobile sensors, blinded for medical professionals and patients. Besides, patients are asked to fill out a short questionnaire one time a day to indicate their current condition and presence of symptoms. Furthermore, nurses will register the presence and corresponding reason for nurse worry in a checklist. At the end of the study period, the feasibility and added value of the wireless vital sign tracking method, patient diary, and nurse checklist are evaluated by patients and nurses using surveys.

The study is realized in a stepwise manner, including a pilot phase (Phase I) to explore the feasibility of the measurement protocol, and an explorative phase (Phase II) for optimization of detection criteria and exploration of the potential of vital sign measurements and decision support methods. Last, a validation phase (Phase III) is performed for verification of the primary endpoints and first evaluation of decision support methods.

Study burden and risks

The quality and availability of vital sign data and robustness of the wireless connection is verified to investigate the technical feasibility of remote vital sign monitoring. The practical feasibility of mobile monitoring system and use of the patient diary and nurse checklist for routine care is explored using the patient and nurse evaluations. This evaluation includes user comfort, user friendliness, time consumption, adherence, applicability, difficulty, and meaningfulness of the methods.
To explore potential decision support methods, we will investigate which vital sign patterns (i.e. absolute values, time trends and shapes) are related with

adverse events using visual inspection and regression analysis. From this knowledge, various statistical models predicting adverse events serving will be tested as novel continuous warning score. To verify whether clinical context information improves detection of adverse events, the accelerometry data, patient symptoms and nurse worry indicators will be integrated in the prediction models.

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

The study population includes two patient groups:
1. Patients aged > 18 years undergoing elective oesophageal and gastric resection admitted to the gastrointestinal surgical ward for postoperative care
2. Patients aged > 70 undergoing hip fracture surgery acutely admitted to the geriatric-

trauma ward for pre- and postoperative care

Exclusion criteria

1. Contraindications for use of vital sign sensor patch (i.e. skin allergy, implanted medical devices, contact isolation, etc.)
2. Diagnosed or suspected delirium, cognitive impairment, or dementia

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-11-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2018
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	22-01-2019
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
CCMO	NL65885.044.18