Supporting early recognition of clinical deterioration for Mobile Vital signs monitoring of high-risk surgical patients

Published: 04-05-2021
Last updated: 04-04-2024

Primary objective: 1. To develop and evaluate a model for prediction of deterioration necessitating escalation of care, based on continuous vital signs recordings, self-reported patient symptoms, nurse observations, clinical measurements, and…

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

Summary

ID

NL-OMON50879

Source
ToetsingOnline

Brief title
MoViSupport

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
: complications, clinical deterioration

Health condition

Pre- en postoperatieve complicaties bij hoog-risico chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente
Source(s) of monetary or material Support: Grants ZGT en Uniiversteit Twente

Intervention

Keyword: Ambulatory monitoring, Clinical deterioration, Decision support models, Vital signs

Outcome measures

Primary outcome

The study will result in the development of a model for prediction of deterioration requiring escalation of care. The model performance will be assessed in terms of sensitivity and false discovery rate for prediction of deterioration requiring escalation of care within 24 hours, and compared with the currently used Modified Early Warning Score.

Secondary outcome

The study will result in:

- Insight in patterns of deterioration, which will be described as characteristics (slopes, absolute values, ratio*s, etc.) observed in vital sign and routine clinical measurements

- Insight in methods that can support personalized detection of patters of deterioration

- Insight in the potential clinical value of models for prediction of deterioration, which will assessed using the time between prediction of deterioration and current clinical response and compared with the currently used Modified Early Warning Score.

Study description

Background summary

Patients admitted to the hospital for surgical care are at risk for developing adverse events in the pre- or postoperative trajectory, which may lead to deterioration requiring escalation of care. To promote patient safety, it is important to recognize and start treatment in an early phase of deterioration. Wireless sensors that allow continuous vital sign tracking with minimal patient burden may aid early identification of deterioration in the hospital ward or out-of-hospital setting.
To facilitate efficient implementation of continuous monitoring in these settings, it is crucial that caregivers are supported in the interpretation of the large amount of data. Current monitoring systems typically use threshold-based alarm systems to detect abnormal vital sign levels. However, these systems are known by high false alarm rates and may miss subtle but relevant trends, related to the fact that the presentation of deterioration differs per patient, per setting, and per type of underlying adverse event. Therefore, there is need for patient specific methods to support early identification of patterns of deterioration that associated with vital instability.

Study objective

Primary objective:
1. To develop and evaluate a model for prediction of deterioration necessitating escalation of care, based on continuous vital signs recordings, self-reported patient symptoms, nurse observations, clinical measurements, and patient characteristics

Secondary objectives:
2. To gain insight in patterns of deterioration that can be observed in continuous vital signs recordings, self-reported patient symptoms, nurse observations and clinical measurements
3. To gain insight in effective methods for personalized detection of patterns of deterioration
4. To explore the potential clinical value of the developed model for prediction of deterioration

Study design

In the current study, we will develop a holistic model to predict deterioration necessitating escalation of care in high-risk surgical ward patients, by detecting patterns based on physiological assumptions. The model is developed and evaluated using an existing study database (MoViSign; NL.65885.044,

2018-2019, ZGT Almelo) and data that is collected in a prospective observational study.

The MoViSign study database includes continuous vital signs recordings and clinical data obtained in high-risk surgical ward patients (N=33 upper GI patients, N=27 hip fracture patients). In the prospective study part, we will obtain additional data in the same population (N*40 upper GI patients, N*40 hip fracture patients) and setting. Accordingly, a wireless sensor will be placed on the patient*s chest during the peri-operative hospital stay for continuous registration of vital signs (ECG, heart rate, respiratory frequency, temperature) and activity level (accelerometry, posture, steps). In addition, continuous vital sign measurements will be performed in the home situation for elective patients two days prior to hospital admission and seven days after discharge. These home measurements aim to collect reference data and explore the potential use of the model for detection of late complications in a home setting respectively. In addition to the vital sign measurements, patients will register symptoms using a daily diary during ward stay and home measurements. Last, nurse worry will be registered by nurses during ward stay.
After completion of data collection, the presence and expected timing of deterioration will be defined for each patient included in the database by two clinical specialists based on the patient record, as gold standard for deterioration events. Next, the total database will be split in a model development set and a model evaluation set. In the model development phase, patterns of deterioration will be described based on physiological assumptions and clinical experience. Next, these pattern descriptions will be translated to detection criteria to predict deterioration based on vital signs recordings, self-reported patient symptoms and nurse observations, clinical measurements, and patient characteristics. Last, the detection criteria will be optimized using case observation in the model development set.
The performance of the resulting model will be evaluated in the model evaluation set in terms of sensitivity and false detection rate, and compared with the performance of the Modified Early Warning Score (MEWS). Last, it will be explored whether this model could contribute to earlier recognition and treatment of deterioration, by evaluating the time between prediction and current clinical response.

Study burden and risks

This study includes two patient groups which have high risk of deterioration due to high rate or large impact of complications during the perioperative trajectory. Accordingly, these patients may particularly benefit from improved methods to support detection of deterioration. As patterns of deterioration may vary per patient group, it is important to conduct the study in the target population and setting.
The study is a non-therapeutic study, and patients will receive care as usual. Individual patients will not experience benefit from participating in this study.

The burden to patients related with the sensor recordings is minimal given the fact that patients will likely not experience any physical discomfort, because the sensor device is a small and noninvasive. As with any measurement using adhesive electrodes or plasters, it is possible that some patients will experience skin irritation in response to the adhesive patches. If skin irritation occurs, the sensors will be removed. The sensor does not restrict daily activities by patients and do not require actions by patients. As an exception, patients will be asked to keep the mobile data receiver charged and in range as much as possible during home measurements.
The patient diary will be provided to the patient on a paper form, including a standard daily questionnaire for registration of the patient*s condition, symptoms, and daily activities (home measurements only). The nature of questions and time needed to fill in the diary will provide minimal burden to the patient.

Contacts

Public
Ziekenhuisgroep Twente

Zilvermeeuw 1
Almelo 7609PP
NL
Scientific
Ziekenhuisgroep Twente

Zilvermeeuw 1
Almelo 7609PP
NL

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 and older) undergoing elective surgery for resection of malignant
tumors of the upper gastrointestinal tract (upper GI patients)
2. Patients aged (70 years and older) undergoing surgery for a hip fracture and admitted to the
hospital for pre- or postoperative care (hip fracture patients)

Exclusion criteria

1. Contraindications for use of vital sign sensor patch (i.e. skin allergy, implanted medical devices)
2. Contact isolation

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-07-2021
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	04-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL76922.100.21