Early recognition of deterioration in high-risk patients using continuous remote wireless monitoring: a clinical observation study with the Checkpoint Cardio system

Published: 25-09-2020
Last updated: 10-04-2024

In the present study we will test the performance of the Checkpoint Cardio sensor solution for the first time in a clinical setting in a limited number of patients at high risk of deterioration. There are three main study objectives: 1. to assess...

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

Summary

ID

NL-OMON54951

Source
ToetsingOnline

Brief title
Wireless monitoring for recognition of patient deterioration

Condition

- Other condition

Synonym
Not applicable

Health condition

Dit betreft een observationele studie met continue metingen van vitale functies bij patiënten met risico op adverse events, welke niet gerelateerd is aan een enkele aandoening of

orgaansysteem

Research involving
Human

Sponsors and support

Primary sponsor: Divisie Vitale Functies
Source(s) of monetary or material Support: Europese Commissie 'Horizon 2020' subsidie

Intervention

Keyword: Patient deterioration, Vital signs, Wearable sensors, Wireless monitoring

Outcome measures

Primary outcome

Study endpoints for Objective 1 (methods comparison analyses):

Respiratory rate, heart rate, blood pressure and arterial blood oxygen saturation derived from sensor data generated during times that the patient is clinically monitored using a wired multi-parameter bedside monitor (for example, while in an operating room, on the recovery room, while admitted to an intensive care or medium care unit).

Study endpoints for objective 2 (detection of deterioration):

a. the occurrence of clinnical deterioration requiring action by caregivers, and

b. the system-calculated *deterioration probability* and hypothetical alerts generated by the test system (sensing system + clinical decision support software) depending on various deterioration probability thresholds.

Study endpoints for objective 3 (usability from a patient perspective):

Usability from a patient perspective will be measured with a short patient interview by phone including 8 questions on a 5-point Likert scale and one question with an open answer. Please see appendix 1: usability assessment.

For a more expensive explanation of the study outcomes, please refer to section 3.4 (Study Endpoints) of the Research protocol.

Secondary outcome

not applicable.

Study description

Background summary

High-risk hospitalized patients * either admitted for acute medical conditions or recovering from major surgery - are at risk for postoperative complications that could result in prolonged hospitalization, hospital readmissions, injury or even death (Sweeney, 2013). Observational studies suggest that unexpected in-hospital ICU admissions or ICU readmissions, cardiopulmonary arrests and death are usually preceded by changes in vital signs 6 to 24 hours prior to these adverse events (Schein, Hazday, Pena, Ruben, & Sprung, 1990). Obvious clinical indicators of deterioration, such as changes in respiratory rate or heart rate are often overlooked and not detected in time (Goldhill, 2004). Known problems are a low nurse-to-patient ratio and infrequent vital signs monitoring. On general wards the current standard is intermittent manual measurement of vital signs, typically only once every nurse shift (every 8 h). In contrast, in high-care settings such as the Intensive Care unit, it is very unusual for acute patient deterioration to be missed, because nurse staffing ratio*s are much higher (1:1, 1:2) and vital signs are continuously monitored using conventional bedside wired monitors. After hospital discharge, vital signs are no longer monitored at all, and the likelihood of delayed recognition of vital instability increases again. Although the risk of sudden patient deterioration typically decreases towards the day of hospital discharge and beyond, the time span that patient deterioration goes unnoticed increases at

each successive care transition from ICU to home..

In an attempt to address the issue of of critical illness and death resulting from missed physiological deterioration, many hospitals have no implemented early warning scoring (EWS) on regular patient wards. In the Netherlands, using EWS is mandatory since 2007. The EWS is designed to alert first-line caregivers to impending adverse events and trigger them to call for help (Bokhari et al., 2010). Despite the potential benefits of early warning scores, many deteriorating patients are still not recognized in time, resulting in significant adverse events and poor outcomes which might have been prevented if the deterioration had been identified earlier (Goldhill, White, & Sumner, 1999). A 2019 consensus-based guideline by the International Society of Rapid Response Systems suggests that hospitals with a well-functioning EWS and Rapid Response System should have near-zero rates of in-hospital cardiac arrests on general wards and recommends that each hospital tracks their in-house cardiac arrests, potential predictability, and timeliness of escalation (Subbe et al., 2019).

*
The Nightingale project has to date resulted in the Checkpoint Cardio prototype system designed to improve safety on general wards by monitoring vital signs continuously using wireless wearable vital signs sensors and combining these data with a clinical decision support system, optimized to timely alert caregivers of patient deterioration.

We previously evaluated the performance of this prototype wireless sensor to be used in this study in adult healthy volunteers (METC 18/579; CCMO: NL67031.041.1). The sensor was highly accurate for heart rate, and accurate for respiratory rate. Continuous noninvase blood pressure tracked exercise-induced small increases in blood pressure. Oxygen saturation (ear probe) was in the normal range, but its performace during hypoxemia could not be evaluated within healthy volunteers breathing room air.

However, despite these encouraging initial results in healthy volunteers, performance in clinically ill patients might differ * there could be more or less artefacts and/or the duration of periods with missing data could be different - for example during episodes of profuse sweating or delirium. We consider accurate *24/7* tracking of heart rate and respiratory rate a minimum requirement for being able to start using these devices clinically as a patient safety monitor.

Study objective

In the present study we will test the performance of the Checkpoint Cardio sensor solution for the first time in a clinical setting in a limited number of patients at high risk of deterioration. There are three main study objectives:

1. to assess the agreement between vital signs measured with the new sensor and a clinical monitoring system currently used on high-care wards (ICU, Medium Care, operation rooms) in our hospital.

2. to evaluate the preliminary accuracy oof the whole system (wireless sensor + clinical decision support software) for the detection of patient deterioration

3. to assess the usability of the system after the initial five days at home after hospital discharge from a patient perspective

Study design

Design: This is a prospective cohort study in which patients receive additional wireless monitoring on top of usual care at the hospital ward and in the first 5 days after hospital discharge. Wireless monitoring is used in a passive way: no warnings are generated by the wireless remote monitoring system nor will it be used to change clinical decisions of patients.

Objective 1 (agreement between sensor values and routine hospital monitors):
We will apply different *methods comparison* techniques to assess the agreement between the wireless sensor values and those obtained with routine hospital monitors. To this end we will make use of the fact that a large proportion of high-risk patients is treated at some point during their hospital stay in a high-care setting (operation room, recovery room, medium care unit, intensive care unit). In these settings continuous (wired) vital signs monitoring is used routinely as a standard of care. We will collect the vital signs data recorded by the routine bedside monitor, which will allow methods comparison techniques such as Bland-Altman analysis, Clarke-Error grids, Four-Quadrant plots) to evaluate the agreement between sensor values and the reference standard (the routinely used wired patient monitor) in *real life* clinical scenarios.

Objective 2 (accuracy to detect clinical deterioration):
We will compare off-line generated *deterioration probabilities* and (theoretical) alerts using various alarm thresholds alerts in relation to the presence or absence of to actual prospectively documented events for prospectively collected observational patient datareflecting relevant clinical deterioration.
The clinical decision support engine of the Checkpoint Cardio wireless monitor system provides a *deterioration probability* and can provide a binary output (*alert*) when the probability of deterioration exceeds a user-defined threshold (in future clinical use this alert threshold will be set by the caregiver, e.g., *send alert IF probability of deterioration > 40% or > 60%*).
This data will be collected both in-hospital and during the first five days after hospital discharge. In addition, data from both the hospital and home period will be retrospectively analysed to evaluate the number of alerts (while varying the probability of deterioration that exceeds certain tresholds) in patients without occurrence of events.

Next to inputs from the wireless vital signs sensor, the clinical decision support engine can also receive inputs from the patient, the nurse, and informal carer, as well as a pre-defined set of inputs from the hospital electronic medical record (age, primary condition, comorbidities, selected most recent laboratory values, as well as trends in those values).
Neither vital signs recorded by the sensor nor any outputs from the clinical decision support system will be visible to the patient and the care team; data will occasionally be visible to study personnel during daytime hours.

Objective 3 (usability assessment):
We will assess the experiences of patients regarding the *usability* of the system, including the more subtle aspects of *wearability* of the sensor. We will also evaluate the ease of sensor application and removal by study personnel, as well as the process of battery change or recharging of the removable battery. Usability will be assessed with patient interviews (please see appendix F1: usability questionnaire) by phone after completion of the study (after the initial five days at home after hospital discharge).

Study burden and risks

In this observational diagnostic study the systems will not send out alerts to caregivers and, as a result, there will not be any additional diagnostic or therapeutic interventions triggered by the system. Hence, all patients will undergo the same routine monitoring by nurses in a systematic manner, and all treatment decisions will be based on current clinical practice (clinical reasoning with inputs from manually recorded vital signs, direct patient observation/examination by nurses and/or doctors, laboratory values and imaging results).

The position of the system used: an adhesive patch sensor placed on the patient*s chest allows measuring vital signs without the inconvenience of physical attachment to immobile monitoring systems. This sensor is lightweight, wireless (no need for cables), and allows untethered measuring of vital signs while in bed or at home. As with any adhesive plaster/tape, it is possible that patients may experience skin irritation in response to the adhesives used, in which case the sensor will be removed. Since physical discomfort from the sensors is unlikely, patient burden will be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* All adult patients (>18 yr of age) who are at high risk for development of serious adverse events receiving care at a surgical or acute medical ward.
* Minimum expected duration of hospital stay > 48h

Exclusion criteria

* known allergy/skin irritation to the adhesives used in the recommended commercially ECG electrodes (alternative electrodes may be offered).
* implanted active medical devices, such as a cardioverter defibrillator or a pacemaker (to avoid potential interference between the different sensing systems)
* a need for contact isolation (to avoid any risk of cross-contamination)

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):	27-11-2020
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Checkpoint Cardio sensor
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-09-2020
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	01-07-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL72404.041.19