Clinical efficacy of continuous remote monitoring compared to intermittent monitoring on a surgical ward in a large European teaching hospital

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Primary Objective: To investigate in surgical ward patients whether the use of wireless continuous vital signs monitoring will reduce total length of hospital stay.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51127

Source
ToetsingOnline

Brief title
Sensible trial

Condition

- Other condition

Synonym
(post-operative) adverse events; failure to rescue

Health condition

post-operatieve complications (rebleeding, infection, myocardial infarction etc)

Research involving
Human

Sponsors and support

Primary sponsor: Albert Schweitzer Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: continuous monitoring, failure to rescue, rapid response system, rapid response team

Outcome measures

Primary outcome

The main study parameter is the total length of hospital stay

Secondary outcome

Secondary endpoints: cardiac arrests, mortality, unplanned ICU admissions,

30-day readmission, RRT calls

Other study parameters are age, gender, % acute admission, charlson comorbidity

index (CCI), international classification disease (ICD), limitation of medical

treatment (LOMT).

Study description

Background summary

In the last decades 10% of all clinically admitted patients in hospitals experienced harm, of which at least 33% of the most severe incidents was due to failure to recognize and treat the deteriorating patient timely on the general wards. Therefore, to improve early recognition and adequate treatment for deteriorating patients, Rapid Response Teams (RRT) have been introduced worldwide since 1995 During a first Consensus meeting it was stated that hospitals should implement an rapid response system (RRS), which consists of four elements: an afferent, "crisis detection" and "response triggering" mechanism; an efferent, predetermined rapid response team; a governance/administrative structure to supply and organize resources; and a

mechanism to evaluate crisis antecedents and promote hospital process improvement to prevent future events, thus implementing a system rather than a team.
But even in hospitals with an established mature RRS, failure to rescue events occur, mostly related to the *afferent limb* of the system, e.g. failure to identify patients at risk. One of the key underlying mechanisms is that the present Rapid Response System (RRS) is based on intermittent monitoring (*spot checks*) every 6-12 hours which may lead to failure to detect a deteriorating patient timely.
For example, a recent study showed that 47% of postoperative patients develop hypotensive periods with a mean arterial pressure < 65 mmHg for at least 15 minutes, while another study showed that more than one third of surgical patients experience an oxygen saturation level of <90% for an hour or more.
Earlier trials showed that continuous monitoring on the general ward (*low care* environments) was associated with a reduced need for patient rescue events or unplanned ICU admissions
Therefore, our aim is to investigate whether wireless continuous vital signs monitoring contributes to timely recognition and treatment of the deterioration patient on a surgical ward resulting in a reduced total hospital length of stay.

Study objective

Primary Objective: To investigate in surgical ward patients whether the use of wireless continuous vital signs monitoring will reduce total length of hospital stay.

Study design

Prospective, interventional single arm trial with historical controls.
The duration of the study is from april 6th to October 5th 2021.
Setting is a general ward in a large European teaching hospital.

Intervention

The intervention group receives at admission continuous monitoring provided by a wireless patch (CE marked; class2a), worn on the patient*s chest, with data transmitted wirelessly every 2 minutes to a mobile device carried by the patient*s nurse.

Study burden and risks

Apart of wearing a wireless patch during the stay at the general ward and completing a single short questionnaire on their experience with wearing a patch, which will take 5-10 minutes, the nature and extent of the burden and

risks are minimal to none.

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

At least 18 years old; surgical, gastroenterology and gynaecological oncology surgical admissions; expected length of stay > 24 h; informed consent

Exclusion criteria

An allergy to skin adhesives, wound or skin lesion near the application site, patients with a pacemaker or implantable cardioverter defibrillator, patients

in a palliative trajectory, patients waiting for placement in a nursery home.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	06-04-2021
Enrollment:	285
Type:	Anticipated

Medical products/devices used

Generic name:	wireless monitoring patch
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-06-2021
Application type:	First submission
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

ID: 26077
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77132.041.21
OMON	NL-OMON26077