Clinical efficacy of Remote continuous Monitoring supplementary to intermittent monitoring compared to intermittent monitoring on a surgical ward in a large Teaching hospital in the Netherlands

No registrations found.

| Ethical review | Positive opinion |
|-----------------------|------------------|
| Status | Pending |
| Health condition type | - |
| Study type | Interventional |

Summary

ID

NL-OMON26077

Source Nationaal Trial Register

Brief title ReMoTe trial

Health condition

surgical, gastroenterology and gynaecological oncology surgical admissions on a general ward

Sponsors and support

Primary sponsor: Albert Schweitzer Hospital, Dordrecht, NL **Source(s) of monetary or material Support:** Albert Schweitzer Hospital, Dordrecht

Intervention

Outcome measures

Primary outcome

total length of hospital stay

Secondary outcome

cardiac arrests, mortality, unplanned ICU admissions, 30-day readmission, RRT calls, experience patients, experience care professionals, alarmfatigue

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 at least three elements: (1) an afferent, "crisis detection" and "response triggering" mechanism; (2) an efferent, predetermined rapid response team; and (3) 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 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 < 65mmHg 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 supplementary wireless continuous vital signs monitoring contributes to timely recognition and treatment of the deterioration patient on a surgical ward resulting in a reduced total length of hospital stay.

Study objective

Remote continuous vital signs monitoring, supplementary to the RRS, contributes to timely recognition and treatment of the deterioration patient on a surgical ward resulting in a

reduced total hospital length of stay.

Study design

6 month trial: total length of hospital stay, mortality, unplanned ICU admissions, 30-day readmissions data is extracted from our EMR; experience patients & care professionals is measured through a single questionnaire; alarmfatigue is measured indirectly through our continuous monitor/ patch system

Intervention

supplementory remote continuous monitoring provided by a wireless patch, worn on the patient's chest, with data transmitted wirelessly every 2 minutes to a mobile device carried by the patient's nurse e.g.

respiratory rate, heartrate and temperature; thus, the continuous monitor functions as an organization's "safety net" for deteriorating inpatients in between the intermittent monitoring of vital signs

in the afferent limb of the RRS.

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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 controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| NL | |
|---------------------------|-------------|
| Recruitment status: | Pending |
| Start date (anticipated): | 22-06-2021 |
| Enrollment: | 285 |
| Туре: | Anticipated |

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

| Positive opinion | |
|-------------------|--|
| Date: | |
| Application type: | |

25-05-2021 First submission

Study registrations

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Followed up by the following (possibly more current) registration

ID: 51127 Bron: ToetsingOnline Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

| Register | ID |
|----------|----------------|
| NTR-new | NL9503 |
| ССМО | NL77132.041.21 |
| OMON | NL-OMON51127 |

Study results