Postoperative remote monitoring of vital signs in older cardiac surgery patients

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To determine the incidence and severity of deteriorating vital signs in frail cardiac surgery patients after ICU discharge using continuous remote monitoring. The central hypothesis of this study is that deteriorating vital signs are common and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON48112

Source
ToetsingOnline

Brief title
AGE AWARE

Condition

- Cardiac therapeutic procedures

Synonym
Frailty, vulnerability

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: EarlySense Ltd, Israel,EarlySense;St Antonius Onderzoeksfonds

Intervention

Keyword: Cardiac Surgery, Elderly, Frail, Remote monitoring

Outcome measures

Primary outcome

The main study endpoint is the occurrence of a vital deterioration.

Secondary outcome

• Drug use.

• Delirium according to delirium observation screening (DOS)

Study description

Background summary

The number of elderly patients scheduled for cardiac surgery is increasing rapidly. An increased life expectancy and improvements in surgical and anesthetic techniques make it possible for older patients to undergo higher risk surgery. Cardiac surgery in elderly patients aims to improve functional capacity and overall survival but may also precipitate major morbidity and mortality. Despite major improvements in the safety of anesthesia and surgery a significant number of elderly patients experience a complication after cardiac surgery.

During the early postoperative period, cardiac surgery patients are routinely monitored at the Intensive Care Unit (ICU). Continuous monitoring of PR, RR and SpO2 enables nurses and physicians to act immediately when vital signs are deteriorating in order to reduce postoperative morbidity. However, the majority of complications after cardiac surgery occur after several postoperative days at the general ward. An explanation for surgery-related complications may be the absence of continuous monitoring and standardized protocols for postoperative care after a patient is discharged from the ICU. Medical deterioration of patients is often preceded by subtle changes of vital signs. Although vital parameters are routinely measured by a nurse at a surgical ward, in many patients these measurements are only performed once every 8 hours. Despite the risk of a significant delay in detection of compromised respiratory or hemodynamic parameters, measurements are often inaccurate or incompletely documented in the medical file due to high working load. As a result, early deteriorations in vital functions are easily missed. To optimize patient safety

and reduce risk of potential inaccurate measurements, continuous remote monitoring of vital signs in high risk patients may be considered as an alternative.

Study objective

To determine the incidence and severity of deteriorating vital signs in frail cardiac surgery patients after ICU discharge using continuous remote monitoring.

The central hypothesis of this study is that deteriorating vital signs are common and often prolonged in older cardiac surgery patients after ICU discharge. Our secondary hypothesis is that treatment with high risk medications in older cardiac surgery patients is associated with deterioration of vital signs.

Study design

• Single center pilot study.
• 100 older patients undergoing cardiac surgery.
• Continuous remote monitoring of vital signs starts at arrival on the general ward after ICU discharge during 3 consecutive days (figure 1).
• PR, RR and SpO2 will be continuously monitored in all patients.
• Patients and healthcare personnel are blinded for monitoring results.
• Main study endpoint is the occurrence of vital deterioration.

Study burden and risks

Remote monitoring of vital signs is without additional risk of the patient. A patient will wear a wireless sensor (arm band with finger sensor and acousitic neck sensor) for 72 consecutive hours.

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

1. Adult patients >=70 years undergoing elective cardiac surgery
2. Frailty, defined by the presence of at least two of the following characteristics:
- Impaired gait speed or hand grip strength
- Risk for malnutrition
- Impaired cognition
- Dependent living
- Impaired physical functioning
- Polypharmacy
- Impaired health related quality of life
- Age >=80 years

Exclusion criteria

• Emergency cardiac surgery
• Transcatheter aortic valve replacement or mitral valve repair.
• No informed consent

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2020
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Remote monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-09-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	06-11-2019
Application type:	Amendment
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
ClinicalTrials.gov	NCT03944967
CCMO	NL68944.100.19