

Image-based remote monitoring in cardiac surgery patients: FORSEE 3 trial

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Main objective: 1. Determine the feasibility, in terms of system fidelity and acceptability, of remote, image-based monitoring in cardiac surgery patients on a general ward. Secondary objectives: 1. The validity of remote, image-based heart- and...

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

Summary

ID

NL-OMON53349

Source

ToetsingOnline

Brief title

FORSEE-3

Condition

- Other condition

Synonym

deterioration after surgery, Postoperative complications

Health condition

Postoperatieve complicaties na hartchirurgie

Research involving

Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis

Source(s) of monetary or material Support: via subsidie "Heart for a sustainable healthcare. Medical devices for early recognition; prevention and treatment of cardiovascular diseases contributing to sustainable healthcare" van ZonMw; NWO; Hartstichting en de Dutch Cardiovascular Alliance (DCVA), Philips

Intervention

Keyword: Cameras, Clinical deterioration, Monitoring, Vitals signs

Outcome measures

Primary outcome

- 1) Percentage of data loss due to
 - Time *out of scope* of patients
 - Privacy window closed
 - Artifacts
- 2) insight in optimal data storage and processing solutions
- 3) insight in user- and patient acceptance of the image-based monitoring technology

Secondary outcome

- 1) Performance of image-based heart- and respiration rate measurements in comparison with the reference devices
- 2) Performance of image-based circadian rhythm measurements in comparison with the reference devices
- 3) The ability of the image-based data to detect clinical deterioration, expressed as sensitivity and specificity
- 4) The predictive value of each image-based parameter in the prediction of deterioration

- 5) Potential time gain in the detection of clinical deterioration
- 6) Optimal positioning, hardware and settings of cameras to gain high quality data in a regular cardiothoracic wardroom
- 7) Insight in correlation of clinical deterioration detected with the image-based monitoring technology and long-term patient outcomes.

Study description

Background summary

In hospitals forty percent of unanticipated deaths occur in low-acuity departments. This alarming figure reflects the limited degree to which the cardiorespiratory status of patients is monitored in these departments, due to the obtrusiveness and expense of existing monitoring technologies, as well as the unpractically high clinical workload and costs that deployment of such technologies would entail. We have previously shown that an image-based monitoring technology reliably estimates heart rhythm and breathing rate under controlled conditions. This project explores image-based monitoring of the cardiorespiratory status of patients as an innovative unobtrusive method that could eventually aid to reduce workload for the staff and better predict (acute) deterioration or adverse events.

Study objective

Main objective:

1. Determine the feasibility, in terms of system fidelity and acceptability, of remote, image-based monitoring in cardiac surgery patients on a general ward.

Secondary objectives:

1. The validity of remote, image-based heart- and respiration rate in comparison with heart- and respiration rate measured with a smart patch
2. The validity of remote, image-based monitoring of circadian rhythms in comparison with a smart patch
3. Discriminative ability of remote, image-based monitoring in the detection of clinical deterioration
4. Time to detection of clinical deterioration with the image-based monitoring technology vs conventional early warning score
5. Predictive value of each camera-based parameter in the detection of postoperative complications
 - a) Heart rate

- b) Respiration rate
 - c) Arrhythmia yes/no
 - d) Facial colour (changes) and potentially other facial cues of illness
 - e) Temperature changes
 - f) Time in bed
 - g) Activity level/ consciousness scale
6. Effect of clinical deterioration detected with image-based, remote monitoring during hospital admission on long term patient outcomes (mortality, complications)

Study design

This is a prospective, observational study in the Catharina hospital, Eindhoven. Patients postoperative after cardiac surgery will be asked to add the camera set-up to their hospital room during their hospital stay. Furthermore, they will wear a smart patch, Healthdot, as CE marked reference device. The study will neither impact the standard of care, nor are the participants subject to procedures or required to follow any rules of behavior. All data will be analyzed retrospectively, and no medical decisions will be made based on the study data. After 12 months, Nederlandse Hart Registratie (NHR) data of study participants will be collected, concerning long-term patient outcomes.

Study burden and risks

Since the proposed technology is completely non-obtrusive there is no additional risk related for the study patients related to the device used. Eventually, when applied in the future, the unobtrusiveness of this technology will increase comfort for patients and reduces workload for the nursing staff. The technique has the potential to support Value-Based HealthCare principles, as it is expected to reduce unexpected adverse events, better risk prediction, shorter hospital stays and increased patient wellbeing by freeing up staff time for the patient.

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

- Age \geq 18 years
- Willing and able to sign informed consent form
- Patients admitted to the cardio-thoracic ward after cardiac surgery
- Planned stay on the cardio-thoracic ward at least 48 hours

Exclusion criteria

- Pregnancy
- Inability to provide written informed consent
- Mental disability
- Language barrier
- Inability to wear Healthdot: known severe allergy for the tissue adhesive used in the Healthdot, any skin condition or use of topicals at the area of application of the Healthdot

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 21-02-2024

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 20-04-2023

Application type: First submission

Review commission: METC Maxima Medisch Centrum (Veldhoven)

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

CCMO

ID

NL83596.015.23