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

Published: 20-02-2023
Last updated: 07-06-2025

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	Completed
Health condition type	Cardiac therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON53349

Source
ToetsingOnline

Brief title
FORSEE-3

Condition

- Cardiac therapeutic procedures

Synonym
deterioration after surgery Postoperative complications

Research involving
Human

Sponsors and support

Primary sponsor: Catharina Ziekenhuis
Source(s) of monetary or material Support: Subsidie Heart for sustainable healthcare van DCVA ZonMW NWO en hartstichting

Intervention

- No intervention

Keyword: Cameras, Clinical deterioration, Monitoring, Vitals signs

Explanation

N.a.

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

Scientific
Catharina Ziekenhuis
I.C. Cramer
Michelangelolaan 2
Eindhoven 5623 EJ
Netherlands
0630603665
Public
Catharina Ziekenhuis
I.C. Cramer
Michelangelolaan 2
Eindhoven 5623 EJ
Netherlands
0630603665

Trial sites

Trial sites in the Netherlands

Catharina-ziekenhuis
Target size: 60

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age >= 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 phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-02-2024
Enrollment:	60
Duration:	1 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N.a.

Ethics review

Approved WMO Date:	20-04-2023
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)
Approved WMO Date:	07-03-2025
Application type:	Amendment
Review commission:	METC MMC

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	NCT06099327
CCMO	NL83596.015.23
Research portal	NL-006288