Video monitoring FOR early Signaling of adverse EvEnts: the validity of camera based detection of irregular heart rate

Published: 29-10-2021
Last updated: 03-03-2024

Irregular heart rate can be detected with a camera-based monitoring technology.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON25838

Source
Nationaal Trial Register

Brief title
FORSEE

Condition

- Cardiac arrhythmias

Health condition

Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Catharina Hospital, Eindhoven University of Technology, Philips Electronics Nederland B.V.
Source(s) of monetary or material Support: This study is part of the research proposal

funded by ZonMw, NWO, the Hartstichting, and the Dutch CardioVascular Alliance (DCVA) of the funding call “Heart for a sustainable healthcare"

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Validity of camera based monitoring to detect irregular heartrate in comparison with ECG

Secondary outcome

- Validity of camera based monitoring to detect respiratory rate and respiratory rate variation compared to those measured with standard contact sensors - Validity of camera based monitoring to detect oxygen saturation and oxygen saturation variation compared to those measured with standard contact sensors - Validity of camera based monitoring to discriminate between different levels of activity - Insight in user and patient experience, focused on clinical staff and subjects

Study description

Background summary

Forty percent of unanticipated deaths and deteriorations in hospitals 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 cost that deployment of such technologies would entail. The FORSEE-project explores video monitoring of the cardiorespiratory status of the patient as an innovative unobtrusive method that could eventually aid to reduce workload for staff and better predict deterioration of adverse events. The main objective of this study is to determine the validity of camera based monitoring to detect irregular heart rate in comparison with ECG. Secondary objectives are the validity of the camera based monitoring technology to detect respiratory rate, oxygen saturation and different activity levels. Another secondary objective is to evaluate user and patient experience. This is an observational study, subjects will be asked to add the contactless camera set-up to the standard procedure. The main endpoint is the correspondence between the camera based heart rate and other vital signs in comparison with the standard contact sensors. All data will be analysed retrospectively and the data collected will be used for algorithm development.

Study objective

Irregular heart rate can be detected with a camera-based monitoring technology.

Study design

Endpoint correspondence between the camera based heart rate and other vital signs in comparison with the standard contact sensors: T0 Camera-based vital signs and reference signals will be collected at least 10 minutes before, during and at least 10 minutes after the cardioversion. This data will be analyzed retrospectively, no clinical decisions will be based on this study data. Endpoint patient experience: T0 Questionnaires will be handed out after the cardioversion and patients will be asked to complete the questionnaire during their hospital stay. T1: When all 48 patients have participated in the trial, a selection of patients will be asked to participate in a focus group (within 3 months after data collection). Endpoint user experience: T0: All involved healthcare providers will be asked to complete a questionnaire about their experience with the video monitoring technology after the cardioversion. T1: When all 48 patients have participated in the trial, a selection of healthcare providers will be asked to participate in a focus group.

Intervention

Videomonitoring

Contacts

Public
Catharina Ziekenhuis Eindhoven
Iris Cramer

0630603665
Scientific
Catharina Ziekenhuis Eindhoven
Iris Cramer

0630603665

Eligibility criteria

Age

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

Elderly (65 years and older)

Inclusion criteria

- Age ≥ 18 years - Willing and able to sign informed consent form - Patients with atrial fibrillation planned for elective cardioversion

Exclusion criteria

- General inmates of psychiatric wards, prisons or other state institutions - Mental disability - Language barrier

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:	N/A , unknown
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-08-2021
Enrollment:	56
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	09-04-2021
Application type:	First submission
Review commission:	METC Utrecht Huispostnr D01.343 Postbus 85500 3508 GA Utrecht 088 755 6376 metc@umcutrecht.nl

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
NTR-new	NL9854
Other	METC MMC : N21.039

Study results