Videomonitoring voor detectie van onregelmatige hartslag

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	Hartritmestoornissen
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25838

Bron
Nationaal Trial Register

Verkorte titel
FORSEE

Aandoening

- Hartritmestoornissen

Aandoening

Atrial fibrillation

Betreft onderzoek met
Mensen

Ondersteuning

Primaire sponsor: Catharina Hospital, Eindhoven University of Technology, Philips Electronics Nederland B.V.
Overige ondersteuning: 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"

Onderzoeksproduct en/of interventie

- Overige

Toelichting

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Leeftijd
Volwassenen (18-64 jaar)
Volwassenen (18-64 jaar)
65 jaar en ouder
65 jaar en ouder

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Leeftijd boven 18 jaar

- In staat om consent formulier te tekenen

- Patienten met atriumfibrilleren gepland voor cardioversie

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Gevangenen of patienten uit een psychiatrische instelling

- Mentale beperking

- Taalbarrière

Onderzoeksopzet

Opzet

Fase onderzoek:	N.V.T.
Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Enkelvoudig
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend
Doel:	Diagnostiek

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	09-08-2021
Aantal proefpersonen:	56
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	09-04-2021
Soort:	Eerste indiening

Toetsingscommissie:	METC Utrecht Huispostnr D01.343 Postbus 85500 3508 GA Utrecht 088 755 6376 metc@umcutrecht.nl

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9854
Ander register	METC MMC : N21.039

Resultaten