The SafeHeart-project

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20961

Bron
NTR

Verkorte titel
SafeHeart

Aandoening

Implantable cardioverter defibrillator.

Ondersteuning

Primaire sponsor: Amsterdam University Medical Centers (AUMC)
Overige ondersteuning: Eurostars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

ICD therapy

Toelichting onderzoek

Achtergrond van het onderzoek

Previous studies have aimed to identify clinical and demographic predictors for therapy delivered by ICDs, albeit no predictors yet have been found to be clinically relevant for wide adoption in the current clinical practice. Consequently, the care for ICD and CRT-D patients is currently reactive and clinicians lack tools to undertake preventive measures. The concept of Artificial Intelligence (AI) emerging as a new method of analysing large, multimodal datasets using different data-sources, potentially enables the development of personalized prediction models for prediction of ICD-therapy occurrence. The primary objective of the SafeHeart-project is to 1) develop a personalized mHealth tool to predict ICD-therapy in study participants with an ICD or CRT-D using a multimodal dataset containing clinical and historical data from electronic health records, remote monitoring-data, behavioural data quantified using accelerometery and patient-reported outcomes (development-study) and 2) asses the feasibility of the SafeHeart mHealth tool in current clinical practice as a proof-of-concept (feasibility-study). This is an international multicenter, observational study aimed to collect data prospectively for individual study participants with an ICD or CRT-D. The participating clinical sites are the Amsterdam University Medical Center (AUMC, location AMC) and Rigshospitalet in Copenhagen (RIGS).The main study endpoint is ICD-therapy (defibrillator shock or antitachycardia pacing (ATP)). Secondary study endpoints include appropriate ICD-therapy alone, incidence of supraventricular arrhythmias, incidence of mortality, heart failure-related hospitalization, mean changes of accelerometer-derived metrics for physical activity and sleep behaviour during follow-up and the health-related quality of life.

Doel van het onderzoek

The aim of this study is to develop a prediction model enabling the prediction of ICD-therapy 30 days in advance (development-study). We will apply two statistical methods of integrating these data in a prediction model 1) a classical multivariate prediction model and 2) a machine learning approach. The second aim is to perform a proof-of-concept clinical feasibility-study using the developed prediction model (feasibility-study).

Onderzoeksopzet

Baseline, 6 months follow-up and 12 months follow-up for the development-study.
Baseline and 6 months follow-up for the feasibility-study

Contactpersonen

Publiek

Amsterdam UMC
Maarten Kolk

020 566 9111

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
− ICD or CRT-D implantation for either primary or secondary prevention less than 5 years prior to enrolment;
− Participation in the remote monitoring program at AUMC or RIGS;
− Patients ≥18 years old
− Having received appropriate or inappropriate ICD therapy or proof of ventricular arrhythmias in the last 8 years prior to enrolment

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation for both the development-study and feasibility-study:
− Unwilling to participate;
− Study participants with a life expectancy of less than one year;
− Study participants with circumstances that prevent follow-up (emigration, change of hospital for follow-up, dropping out of the remote monitoring program);
− Study participants who are unable to wear the accelerometer wrist-band (e.g. allergic to the material);
− Clinically unstable study participants;
− End-stage of heart failure (NYHA-class IV);
− Study participants unable to complete a questionnaire;

– Does not understand the local language (Dutch or Danish);
– Serious physical disability (e.g. wheelchair-bound);
– A planned ablation for ventricular tachycardia (VT);
– Significant movement disorder (i.e. hemiplegia or Parkinson’s disease or similar).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2021
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	21-01-2021
Soort:	Eerste indiening

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	NL9218
Ander register	METC AMC : METC 2020_248

Resultaten