The SafeHeart-project

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20961

Source
NTR

Brief title
SafeHeart

Health condition

Implantable cardioverter defibrillator.

Sponsors and support

Primary sponsor: Amsterdam University Medical Centers (AUMC)
Source(s) of monetary or material Support: Eurostars

Intervention

Outcome measures

Primary outcome

ICD therapy

Secondary outcome

Mortality, MACE, hospitalization, SVT onset, quality of life

Study description

Background summary

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.

Study objective

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).

Study design

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

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2021
Enrollment:	400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	21-01-2021
Application type:	First submission

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	NL9218
Other	METC AMC : METC 2020_248

Study results