Personalized and preventive mHealth predicting life-threatening arrhythmias in cardiac patients

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To develop a prediction model for ICD-therapy in a study population of ICD and CRT-D patients using a multimodal dataset containing clinical and historical data from electronic health-records, remote monitoring-data, accelerometer-derived data and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON50154

Source
ToetsingOnline

Brief title
The SafeHeart project

Condition

- Cardiac arrhythmias

Synonym
Cardiac arrhythmias, heart rhythm disorder

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Eurostars Eureka;RVO

Intervention

Keyword: Artificial intelligence, Digital Health, Implantable cardioverter-defibrillator, Life-threathening ventricular arrhythmia

Outcome measures

Primary outcome

The main study endpoint is the occurrence of inappropriate or appropriate

ICD-therapy between baseline and 12-months follow-up.

Secondary outcome

Time to appropriate/successful ICD-therapy (shock, ATP);

Cumulative incidence of ICD-therapy, both inappropriate and appropriate therapy

Time to inappropriate ICD-therapy (shock);

Incidence of unnecessary ICD-therapy;

Change in accelerometer-derived physical activity from baseline until 12-months

follow-up by activity type data related;

Change in accelerometer-derived sleep behavior from baseline until 12-months

follow-up for different sleep-related metrics;

Number of unique AF episodes from baseline until 12-months follow-up

Cumulative duration of AF during the observation period

Change in device-derived (D-PA) physical activity from baseline until 12-months

follow-up.

Mean of autonomics (night heart rate, heart rate variability) during 12-months

follow-up

Mean ventricular rate during episodes of AF.

Incidence of and time to hospitalization (cardiovascular events, heart

failure), mortality (all-cause, arrhythmic death, cardiovascular death, unexplained) and Major adverse cardiac events (MACE);

Functional change from baseline onwards per NYHA functional classification;

Incidence of ICD-related complications (device infection, lead dislocation, generator-related complications);

Comparison of patient-reported health-related quality of life at baseline and at 12-months follow-up between patients with ICD-therapy and patients free of ICD-therapy.

Study description

Background summary

Previous trials have identified several clinical and demographic predictors for life-threatening ventricular tachyarrhythmias (VTAs) and appropriate therapy delivered by an implantable cardioverter-defibrillator (ICD) or ICD with cardiac resynchronization therapy (CRT-D). The introduction of the concept of Artificial Intelligence (AI) as a new method of analyzing large datasets enables the development of new, personalized prediction models for VTA occurrence aside from the current prediction models. In 2019, Shakibar and collegues devolped a machine learning (ML) model for the prediction of electrical storms. The ML random forest performed significantly better than logistic regression ($p<0.01$), achieving a test accuracy of 0.96 and an area under the curve (AUC) of 0.80 (vs. an accuracy of 0.96 and an AUC of 0.75 achieved with logistic regression). The percentage of ventricular pacing and the daytime activity were the most relevant variables in the prediction model.

Study objective

To develop a prediction model for ICD-therapy in a study population of ICD and CRT-D patients using a multimodal dataset containing clinical and historical data from electronic health-records, remote monitoring-data, accelerometer-derived data and study participant-reported outcomes. The incidence of ICD-therapy (composite endpoint of appropriate and inappropriate therapy) is the dependent variable of the prediction model. Specific metrics and outcomes will be obtained from these data-sources, selected by considering clinical reasoning (i.e., commonly applied in clinical practice), relevant

literature (e.g., a systematic review of the literature), and/or knowledge of experts in the field.

Study design

The study involves a cohort of 400 patients who have received an ICD or CRT-D. Patients will be recruited in both hospitals AUMC and RIGS; 200 study participants will be recruited in each hospital. Study participants will be recruited during the same time period from December 2020 onwards. The enrollment of study participants will be ongoing for a duration of an estimated 2 years and includes 12 months of follow-up (period 2020-2023), depending on the patient adherence to the wearable. Enrollment in the study does not interfere with the standard care for ICD or CRT-D study participants. There will be four main data sources 1) Clinical data will be collected retrospectively from the electronic health records. Clinical event data will be collected prospectively (e.g. MACE, mortality, hospitalization), 2) External accelerometer (wearable) data for the duration of 12 months 3)Remote monitoring data including device programming settings, appropriate and inappropriate ICD shocks, anti-tachycardia pacing (ATP) therapy and intracardiac electrograms will be collected and added to the data set 4) Patient-reported data (e.g. symptoms such as chest pain, palpitations and dyspnea, weight) will be obtained using diaries 5) Questionnaires related to the health-related quality of life and the ICD.

Study burden and risks

We assess the burden of this study for the patients to be low. They will wear the wearable acclerometer for ultimately 365days, which is comparable to wearing a watch. Besides, patients are alllowed to remove the wearable in case of special activities or occasions, for instance in case they are planning to do a contact sport where the wearable could do harm. Also, patients are allowed to remove the wearable for a specific period in time, for instance when they are going on a holiday. Patients will be asked to fill out questionnaires at three moments, these questionnaires are related to their quality of life and the ICD-device. Patients are not exposed to intimate or private topics in these questionnaires.

The risk of this study is very low. Patients are not exposed to risks during the study. No intervention is performed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients >=18 years old and have undergone ICD or CRT-D implantation for either primary or secondary prevention less than 5 years prior to enrollment;
- Are participating in a remote monitoring program at AUMC or RIGS;
- Having received appropriate or inappropriate ICD therapy or ventricular arrhythmias in the last 8 years prior to enrollment.

Exclusion criteria

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);
Study participants who are unable to wear the GENEAactiv wrist-band (e.g. allergic to the material);
Clinically unstable study participants;
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 Parkinsons disease or similar)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-06-2021
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	18-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
CCMO	NL75308.018.20