ELECTRIC-AI pilot study: The evaluation of patient-reported symptoms in remote monitoring care of ICD patients

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Objective: To collect patient-reported symptoms, device data, and the clinical follow-up action of each remote transmission to develop an automated triage workflow that can discriminate between actionable and nonactionable evaluations. In addition,...

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

Summary

ID

NL-OMON57164

Source
ToetsingOnline

Brief title
ELECTRIC-AI

Condition

- Cardiac arrhythmias

Synonym
ICD or CRT-D carriers, ICD or CRT-D patients

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Abbott,TKI project met PPP allowance

Intervention

Keyword: ICD patients, patient-reported symptoms, remote monitoring, triage algorithm

Outcome measures

Primary outcome

The main study endpoint is the actionability of the follow-up action corresponding to each remote device and symptom transmission. Second endpoint is the usability, assessed by evaluating the ease of use through a standardized questionnaire (UMUX) and semi-structured interviews (n=5). Moreover, the data collected during this study will be used to develop an automated triage algorithm for remote transmissions.

Secondary outcome

Additional secondary endpoints will contain the results of the EQ-5D, KCCQ-12, and HADS questionnaires and primary outcome measures for a subsequent randomized controlled trial (e.g. non-actionable in-person evaluations, safety endpoint (MACE/SAE), appropriate and inappropriate ICD-therapy, quality of life, anxiety scores, and time to diagnosis of a clinical event).

Study description

Background summary

Rationale: Remote monitoring (RM) is now considered the gold standard for follow-up care of patients with an implantable cardioverter defibrillator (ICD). Despite the potential of RM, there are important limitations of RM in real-world clinical practice, including a lack of patient-reported outcomes and symptom status, high rates of non-actionable hospital visits, and a complex infrastructure that requires a dedicated team. With the ageing population, rising healthcare costs, and a shortage of healthcare personnel, it is critical to improve the RM infrastructure. We hypothesize that supplementing the remote

device data with patient-reported symptoms, could improve the efficiency of the process. Leading to less non-actionable in-hospital visits and earlier identification of patients at high risk.

Study objective

Objective: To collect patient-reported symptoms, device data, and the clinical follow-up action of each remote transmission to develop an automated triage workflow that can discriminate between actionable and nonactionable evaluations. In addition, we want to assess the usability of symptom registration with a mobile application for a diverse group of ICD patients. Secondary objectives are evaluating the effect of symptom reporting on the quality of life of patients and investigate trends in symptoms, device data, and clinical outcomes. Third, we aim to collect a comprehensive remote monitoring dataset that can be used for the development of an automated triage algorithm.

Study design

Study design: This is a single-center, prospective, and observational study aimed to collect patient-reported symptoms and device data from study participants with a Gallant* ICD or Gallant* CRT-D (Abbott). The participating clinical site is the Amsterdam University Medical Center (AUMC, location AMC and VUmc). Patients use the Castor Connect smartphone application to report their symptoms, in addition to their standard-care pathway for one year. Symptom tracking will occur with a standardized questionnaire developed by the AUMC based on clinical expertise. A purposive sample of study participants (n=5) will be invited to participate in semi-structured interviews to gain insight into how outcomes of triage could in future be presented back to patients, closing the feedback loop. Preliminary feedback options generated through co-creation will be evaluated in semi-structured interviews with this sample of participants.

Study burden and risks

Participants will not be exposed to risks associated with the use of the application, as it serves as a data collection tool that is used alongside regular care. Participants will be asked to use the application at least weekly, this will take 2 to 15 minutes. The focus on symptom reporting, could potentially impact the quality of life or anxiety levels of a patient. This will be evaluated during the study. Participants need to visit the hospital once, during the baseline visit at the initiation of the study. Halfway through the follow-up period and at the end of the study the patients will receive a call from the researcher. If patients are selected (n=5) for the semi-structured interviews to evaluate the usability of symptom reporting in the mobile application, they will have to visit the hospital for a meeting of

one hour. Patients will be able to decline participation in the semi-structured interviews without further consequences for their participation in the main study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Implanted with a Gallant* ICD or CRT-D device
- Participation in the remote monitoring program at AUMC
- Patients >=18 years old

Exclusion criteria

- Not able to provide written informed consent
- Not able to use the Castor Connect application
- A life expectancy of less than one year
- Insufficient understanding of the Dutch language

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2024
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-11-2024
Application type:	First submission
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	NL87437.018.24