Implementing Self management using eHealth for monitoring and management after Catheter ablation in the treatment of Atrial fibrillatioN.
A study on the diagnostic accuracy and the effects of eHealth rhythm monitoring on patient related outcomes, clinical management and health outcomes.

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Optimise post PVI management using ambulant continuous patient-driven eHealth monitoring after catheter ablation in the treatment of atrial fibrillation.Primary Objective:1) Determine the effect of eHealth on clinical management, outcomes and...

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

Summary

ID

NL-OMON44247

Source
ToetsingOnline

Brief title
iSCAN

Condition

- Cardiac arrhythmias

Synonym
atrialfibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atrial fibrillation, eHealth, monitoring, self management

Outcome measures

Primary outcome

Effect on post-PVI management:

- Arrhythmia detection (AF, Aflut, AT, SVT)

- Time until arrhythmia detection

- Medication management (AAD, OAC)

- Time until discontinuation AAD and OAC

- Healthcare Consumption

Secondary outcome

- diagnostic accuracy studie

1) sensitivity

2) specificity

3) positive and negative predicting values

4) Cohens kappa Kardia - Holter, Kardia application - Cardiologist

- Usefulness and applicability eHealth

1) ease of use

2) availability when demanded

3) technical quality

4) compliance

5) User satisfaction (patient and physician)

6) Quality of Life

Study description

Background summary

Atrial fibrillation is a major public health problem and is the most common cardiac arrhythmia, affecting an estimated 4.5 million people in Europe. The true prevalence of atrial fibrillation is likely underestimated because episodes are often sporadic; therefore, it is challenging to detect and record an occurrence in a *real world* setting. Catheter ablation, pulmonary vein isolation (PVI), has shown to be a safe and effective treatment strategy for AF and therefore it has become an established invasive strategy for drug refractory AF.
After PVI, 30-60% of patients show recurrent episodes of AF. Previous studies have demonstrated that the overall prevalence of undiagnosed AF is underestimated, and active screening and monitoring should be pursued. Prompt recording of a 12-lead ECG is an effective and cost-effective method to document chronic forms of AF, but paroxysmal AF is more often missed. The technology to detect paroxysmal, self-terminating AF episodes is rapidly evolving. Evidence shows that prolonged ECG monitoring enhances the detection of undiagnosed AF. The detection of asymptomatic and paroxysmal AF by new technologies, such as smartphone cases with ECG electrodes, smart watches, and blood pressure machines with AF detection algorithms, has not yet been formally evaluated against an established arrhythmia detection method, but looks promising. The use and implementation of electronic-health (eHealth) is being encouraged by the Hearth Rhythm Society(HRS) and European Hearth Rhythm Association (EHRA), as stated in their position statements of 2012 and 2015.
This study will evaluate a mobile eHealth device to detect recurrent atrial arrhythmias after PVI and to evaluate the impact on patient outcomes and quality of life.

Study objective

Optimise post PVI management using ambulant continuous patient-driven eHealth monitoring after catheter ablation in the treatment of atrial fibrillation.

Primary Objective:
1) Determine the effect of eHealth on clinical management, outcomes and quality of life compared to standard of care follow up

Secondary Objectives:
1) Determine the diagnostic performance and reliability
2) Determine the usability and applicability in daily practice.

Study design

Longitudinal cohort study

Study burden and risks

Patients receive additional means for cardiac rhythm monitoring to encourage self-management and early detection. Thereby, recurrent cardiac arrhythmias might be recognised earlier and improved quality of life might be achieved earlier. Standard of care will not be restricted unless the treating cardiologist deems it appropriate.

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 and over
* a history of documented palpitation driven paroxysmal atrial fibrillation or symptomatic persistent atrial fibrillation.
* Scheduled for index PVI procedure
* Already utilises a smartphone or tablet compatible with required software prior to enrolment

Exclusion criteria

* Patients monitored with continuous heart rhythm monitor (e.g. PM, ICD, ILR)
* Participation in a conflicting study

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2018
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	AliveCor Kardia Mobile
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-07-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 22619
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL62457.100.17
OMON	NL-OMON22619