iSCAN: Implementing Self management using eHealth for monitoring and management after Catheter ablation in the treatment of Atrial fibrillatioN.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22619

Source
NTR

Brief title
iSCAN

Health condition

Atrial Fibrillation (AF)
eHealth
Ambulant monitoring
Monitoring
Catheter ablation
Pulmonary vein isolation (PVI)
diagnostic accuracy study

Sponsors and support

Primary sponsor: St. Antonius Ziekenhuis te Nieuwegein (afdeling Cardiologie)
Source(s) of monetary or material Support: St. Antonius Research fund

Intervention

Outcome measures

Primary outcome

(1) Detection and time till detection of recurrence of AF

(2) Use of medication post PVI

(3) Time until AAD are ceased

(4) Quality of Life (AFEQT-questionnaire)

(5) Healthcare visits (cardio-vascular related)

(6) additional diagnostic testing

Secondary outcome

(1) Diagnostic accuracy study pre PVI and post PVI

• Sensitivity and specificity

• Positive predicting value and negative predicting value

• Compare the diagnostic accuracy to continuous monitoring during 7-day Holter for AF.

• Intra and interobserver agreement using the kappa coefficient between the Kardia Mobile and 7-day Holter

• Intra and interobserver agreement using the kappa coefficient between the Kardia Mobile application and a cardiologist

(2) Applicability and usefulness post PVI

• Usability

• Availability (regular and on demand (symptom driven))

• Quality of the recordings (ECG strips)

• Compliance of symptomatic patients, daily and on demand

• Compliance of asymptomatic patients, daily and on demand

• Effect on emotional, social and behavioural aspects

• Patient satisfaction on the use and functionalities of the device and application

• Physician satisfaction on the use and functionalities of the device and application

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 (Kardia) to detect recurrent atrial arrhythmias after PVI and to evaluate the impact on patient outcomes and quality of life.

Objective of the study:

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 after pulmonairy vein isolation in the treatment of AF.

Secondary Objectives:

1) Determine the diagnostic performance/accuracy and reliability

2) Determine the usability and applicability in daily practice.

Study design: Longitudinal cohort study

Study population: 100 patients who undergo catheterablation for AF

Primary study parameters/outcome of the study:

Effect on post-PVI management:

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

2) Time until arrhythmia detection

3) Medication management (AAD, OAC)

4) Time until discontinuation AAD and/or OAC

5) AF-related healthcare visits

Secundary study parameters/outcome of the study (if applicable):

Diagnostic accuracy study

1) Sensitivity

2) Specificity

3) positive and negative predicting values

4) Cohens kappa Kardia (holter – kardia and kardia – 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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):

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.

Study objective

(1) Time until documented recurrence of AF or SVT will be shorter in the study population compared to the standard of care.

Study design

- informed consent

- prior to ablation concomitant 7-day holter and use of eHealth (diagnostic accuracy study)

- post ablation continuous eHealth use in addition to regular care

- study contact/visits 4, 8 and 12 months

*(1) symptoms, medication and health care visits

*(2) AFEQT (quality of life - atrial fibrillation)

*(3) eHealth questionnaire about applicability and usability

Holter after 12 months

Intervention

patients recieve an eHealth mobile device to monitor for recurrence of AF or other SVT during the first year after ablation

Contacts

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Eligibility criteria

Inclusion criteria

(1) Patients 18 years and over

(2) Documented palpitation driven paroxysmal atrial fibrillation or symptomatic (long-standing) persistent atrial fibrillation

(3) Scheduled for index PVI procedure

(4) Succesfully utilises a smartphone or tablet, compatible with the required software prior to enrolment

Exclusion criteria

(1) Patients monitored with continuous heart rhythm monitor (e.g. pacemaker, ICD, ILR)

(2) Participation in a conflicting study

(3) Inability or unwillingness to complete the full study protocol

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2018
Enrollment:	100
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-03-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44247
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6956
NTR-old	NTR7144
CCMO	NL62457.100.17
OMON	NL-OMON44247

Study results