Personalized approach using wearable technology for early detection of Atrial Fibrillation (PATCH-AF)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON54154

Source
ToetsingOnline

Brief title
PATCH-AF study

Condition

- Cardiac arrhythmias

Synonym
arrhythmia, Atrial fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: ZonMw,Ksyos Expertise Centrum

Intervention

Keyword: Atrial Fibrillation, Diagnosis, Electrocardiography, Primary Health Care

Outcome measures

Primary outcome

The main study parameter will be the difference in the number of patients with newly found AF between the intervention and control arms over three years of follow-up.

Secondary outcome

1. Difference in incident AF yield between the screened patients in the interventionarm and all patients in control arms

2. Difference in time to diagnosis of AF between intervention and control practices.

3. Difference in other relevant cardiovascular outcomes like stroke, TIA, dementia, heart failure and use of anticoagulation therapy.

4. Difference in detection of new AF in control practices participating in the trial versus detection of AF in non-participating general practices in the network.

5. Patient experience with the monitoring device in the intervention group and how they think about the implementation of AF screening in the future.

Study description

Background summary

Atrial fibrillation (AF) is a cardiac arrhythmia with a lifetime risk of approximately one in four. The presence of AF strongly increases one person*s

risk of stroke and, heart failure. There is furthermore growing evidence that AF is an independent risk factor for cognitive decline and dementia. Currently, one in five strokes is related to undetected AF. Approximately 60% of these strokes could have been prevented if AF would have been detected earlier and prophylactic anticoagulant therapy would have been started. However, in daily practice detecting AF can be quite challenging, as it often occurs in a paroxysmal form, meaning that many cases are left undiagnosed and thereby exposed to stroke when only using a single time-point assessment. Fortunately, due to advances in technology, we are now able to increase the chance of detecting paroxysmal AF with patient-friendly, non-obtrusive cardiac monitoring devices that allow for continuous arrhythmia detection for up to 7 days. This sets the stage for a program that targets individuals at high risk for AF for selective screening with this new technology. Epidemiological studies show that mostly patients aged 65 and older are at high risk of developing AF. Moreover clinical risk scores have been developed that can further risk-stratify individuals. The CHA2DS2-VASc score, developed to determine initiation of anticoagulant therapy in patients with AF, also has the ability to predict the risk of AF and appears most favorable due to its ease-of-use and compatibility with electronic health records. We therefore aim to evaluate the diagnostic yield for AF when using continuous cardiac monitoring in older patients deemed at high risk (based on CHA2DS2-VASc) compared with routine practice.

Study objective

The primary objective will be evaluating the difference in detection of new AF between the intervention practices (yearly 7 days AF screening with continuous heart rhythm monitoring) and control practices (care as usual) over three years of follow-up.

Study design

General practice based, network-run, cluster-randomized controlled trial (RCT) with randomization at the practice level. The network concerns the *Academisch Huisartsennetwerk AMC*, which includes data from almost a half million patients in the Amsterdam region. The network database is fed with information that is received quarterly via automated data extractions from the affiliated general practices. Study duration is three years.

Intervention

7-day ECG- monitoring using the Bittium Faros 360 at baseline (t=0), after one(t=1) and two years (t=2).

Study burden and risks

A burden for participants consists of wearing the 7 day ECG monitor.The main

side-effect of the ECG monitor could be a local skin allergy requiring to remove the monitor and end the intervention. No other health risks are involved for participants. Patients might benefit in an early diagnosis of atrial fibrillation and hereby early treatment leading to a reduced risk of complications such as ischemic stroke. Furthermore participants will fill out a questionnaire after the first and third screenings round.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

Aged 65 and over
Not diagnosed with atrial fibrillation
CHA2SD2VASc score of 4 or more for women and 3 or more for men

Exclusion criteria

Legal incompetence
Pacemaker/ICD

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-10-2021
Enrollment:	930
Type:	Actual

Medical products/devices used

Generic name:	Bittium faros 360 ecg monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-07-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-11-2021

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-02-2022
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

ID: 22716
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL76925.018.21
OMON	NL-OMON22716