Detection and Quantification of Atrial Fibrillation in High-Risk Patients Using a Smartwatch Wearable (Apple Watch) with a Photoplethysmographic sensor and ECG-functionality

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

Summary

ID

NL-OMON56124

Source
ToetsingOnline

Brief title
AF detection in High-Risk Patients with an Apple Watch

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: Bob Vlake Foundation

Intervention

Keyword: Apple Watch, Atrial Fibrillation, High-Risk Patients

Outcome measures

Primary outcome

The primary study parameter is the incidence of atrial fibrillation detected by

the PPG sensor and Apple algorithm and diagnosed by a cardiologist

(intervention group) or by standard care alone.

Secondary outcome

The secondary outcomes are time to event, the initiation of therapies for AF,

the number of patients with major adverse cardiovascular events, other

arrhythmias than AF diagnosed by a cardiologist, predictors of AF and number of

emergency department visits during the study period.

Study description

Background summary

Atrial fibrillation (AF) is the most common arrhythmia in the elderly population and has become one of the most important public health issues and causes of health expenditures in Europe over the last two decades. People with AF may present with symptoms, but asymptomatic episodes are also possible, especially in paroxysmal AF, where an episode of AF terminates spontaneously and could remain undiagnosed until complications such as stroke occur. The lack of continuous heart rate monitoring options makes early diagnosis of AF challenging. In this trial, a PPG smartwatch wearable (Apple Watch series 5 or 8) will be used to conduct continuous heart rate and -rhythm monitoring in cardiac patients with a known high risk of developing AF (ChadsVasc score >= 2 men; >=3 women; age >= 65). Collected data will be transferred to a smartphone

ECG-application (Apple) and analysed by an algorithm (Apple). All equipment has been clinically validated and CE marked for this use. A control group will follow their standard
care and is investigated to give insight in the role of adding a PPG smartwatch to standard care. The aim of this trial is to identify, diagnose and treat otherwise undetected AF in a high-risk group of cardiac patients and thereby lower the risk of future complications of AF.

Study objective

The primary objective of this trial is to quantify the incidence of AF in patients at high risk for but without previously known AF using a smartwatch wearable with a photoplethysmographic sensor and to determine if the incidence is higher compared to patients receiving standard care alone.

Study design

A monocenter, prospective randomized conrolled trial in high-risk cardiac patients (ChadsVasc score >= 2 men; >=3 women; age >=65).

Study burden and risks

Participants in the intervention group are requested to wear an Apple watch for a minimum of 12 hours a day, which will be handed to them during a screening visit. Simultaneously, they will need to have a connected smartphone with them. When an irregular heartbeat is detected by the PPG signal, patients are notified on the smartwatch and requested to record a single-lead ECG of 30 seconds. If necessary, participants may be asked to visit one of the outpatient clinics of the Investigator for additional testing. In case of symptoms or distress participants are instructed to contact a physician or the emergency number. Patients are requested to perform extra measurements if symptoms occur. After the monitoring period of 6 months, an evaluation visit is scheduled in which the devices will be returned to the Investigator. Patients in the control group will receive their standard care alone and will not wear an Apple Watch. The risks of participation are negligible for all patients. The study requirements for careful selection, training, and
monitoring of the participants for 6 months carry potential benefits that might not be present if the subject received the device without participating in the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Elderly (65 years and older)

Inclusion criteria

- High risk, defined as patient ChadsVasc >=2 for men and or >=3 women at time of eligibility screening
- Patient age >= 65 years at time of eligibility screening
- Possession of iPhone (5s or later) with iOS version 11.0 or later defined as iPhone model/iOS version used to complete screening eligibility

Exclusion criteria

- Diagnosis of Atrial fibrillation or Atrial Flutter
- Currently on anticoagulation therapy
- Cardiac implanted electronic device (Pacemaker, ICD)

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-11-2022
Enrollment:	436
Type:	Actual

Medical products/devices used

Generic name:	Smartwatch
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-01-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2023
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	NL79151.018.21