Performance of commercially available SmartWatch-based electrocardiography to identify atrial fibrillation during exercise testing: the WATCH-ECG study

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

Summary

ID

NL-OMON50030

Source
ToetsingOnline

Brief title
WATCH-ECG study

Condition

- Cardiac arrhythmias

Synonym
Afib, irregular heart rhythm

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Atrial fibrillation, Cardiovascular App, Rhythm detection, Smartwatch

Outcome measures

Primary outcome

Main study endpoint

This study is designed to assess diagnostic accuracy, as defined by sensitivity

and specificity, of a commercially available heart rate monitor (Apple Watch)

in detecting AF during tachycardia. Details of the device are provided in this

chapter.

Secondary outcome

None.

Study description

Background summary

Atrial fibrillation (AF) affects millions of patients worldwide and is a cause of substantial morbidity and stroke. Asymptomatic AF is gaining worldwide interest for its potentially serious clinical consequences.(1) Furthermore, paroxysmal AF may evolve into persistent or permanent AF when left untreated. Screening and early detection of this * in its paroxysmal stage somewhat elusive * arrhythmia may lead to reductions in stroke, hospitalizations and death due to early treatment initiation.

The Apple Watch (series 4) is among the first commercially available devices capable of a single-lead electrocardiographic (ECG) registration using electrodes embedded within components of the device (Figure 1). The ECG application algorithm detects whether atrial fibrillation is present and medical expertise should be consulted. Data from these recordings are encrypted and users will be able to share a report with their doctors via PDF. De Novo classification for this technology was recently obtained by the FDA, making it the second consumer device to gain Class II clearance for ECG monitoring.(2)

Extensive research using deep neural networks has been conducted to test the accuracy of heart rate detection using photoplethysmography (PPG) in older models.(3) The model exhibited a C-statistic of 0.97 to detect AF against the reference standard 12-lead ECG-diagnosed AF in a validation cohort of 51 patients undergoing cardioversion; sensitivity was 98.0% and specificity was 90.2%.The authors may be applauded for this effort to improve early detection rhythm assessment, which will undoubtedly prove valuable in reducing AF-related complications in the future. However, the performance of the new AF detection algorithm using electrocardiographic data, especially in more challenging real-world situations, is yet to be determined. Despite the fact that this is promising technology, attention should be paid to its potential limited accuracy in younger users and patients with concomitant heart disease.

Screening using the AliveCor Kardia monitor has proven to be significantly more effective in identifying AF than routine care in patients > 65 years of age.(4) However, AF detection may be less accurate at higher heart rates and during distorted signals and artifacts caused by physical exertion. Therefore, younger and more physically active users of this device * a large relatively healthy population * may be at risk of receiving AF notifications during exercise and other causes of tachycardia, potentially leading to unnecessary out-patient visits or even wrongful diagnosis. Herein lies this new wearable technology*s main pitfall and source of skepticism by some health care providers. We seek to further determine whether this is concern is justified, or whether this commercially available noninvasive screening tool has the potential to expand the diagnostic arsenal for AF.

Study objective

The objective of this study is to determine the performance, as defined by sensitivity and specificity, of the commercially available Apple Watch-based electrocardiographic registration to identify AF during tachycardia, validated against the gold standard 12-lead electrocardiography.(5)

Study design

Type of study:
This is an acute prospective non-randomized single-arm monocenter study to evaluate an additional diagnostic tool in adult patients that were already scheduled for routine exercise testing. The study is set to start on April 1st 2019. All data will be collected in the Academic Medical Center in Amsterdam. All participants will be asked for written informed consent prior to enrolment.

Sample size:
No data on test performance of this specific technology has previously been reported and the difference in diagnostic accuracy between the device and the reference standard is yet to be determined. In this explorative, observational

study, we estimated that 70 enrolled patients will provide enough information to determine diagnostic accuracy.

Study methodology:

Study procedure
DuringBefore their planned visit to the cardiology outpatient clinic in which the exercise test was planned, eligible subjects will be informed about the study. Hence, the conduct of this study will not influence the indication for exercise testing. During the visit, the subject information sheet (SIS) containing information on purpose, background, participation and risks of the study will be handed for further reading. After sufficient time to read and process the information the subject will asked for written informed consent. The in-hospital exercise test (either on treadmill or ergometer) during routine care will mimic real world exercise. Tachycardia is defined as a heart rate >100 bpm. In case this target frequency is not reached, the subject will be excluded from analysis. Rhythm evaluation with the investigational device will be performed in the recovery phase of the exercise test. This way, the patient can use both hands as normal during the high intensity exercise phase, avoiding the additional risk of falling due to instability. In case of participation, the subject will receive the device on their left wrist (before the exercise test) and place their right index finger on the crown of the watch (during recovery phase), as indicated by the manufacturer. In case this not possible, the right arm may be used instead.
An electrocardiographic registration of around 30 seconds will be made, after which the device algorithm indicates the registered heart rhythm, being either sinus rhythm or atrial fibrillation. This process may be repeated up to three times in total during the recovery phase in case of failed rhythm detection. A 12-lead ECG as part of the routine resting will be obtained simultaneously to ensure synchronous analysis of heart rhythm between the two methods of diagnosis. No personal information will be stored on the Apple Watch and no additional measurements of any kind will be obtained from it.
Patient safety during exercise testing will be warranted by adherence to local safety protocol for exercise testing. A research fellow will be present to aid in device positioning and to record its findings on the anonymized case report form (CRF), along with baseline characteristics on age, gender, BMI and medical history. Concurrent 12-lead ECG interpretation by an experienced physician will serve as the gold standard in diagnosing AF. Subjects serve as their own controls in the evaluation in difference in proportions between two within-subject observations of the outcome.

The device under investigation is the Apple Watch series 4 (released September 2018 by Apple Inc., Cupertino, CA, USA), and obtained clearance by the Food and Drug Administration (FDA) as a class II medical device. A number of these devices will be purchased by the department of cardiology to conduct the study. If over the course of this study, new models of the Apple Watch become approved for use, the protocol allows the use of newer series that are market approved

with similar instructions by the regulatory authorities in the country of the study center.

Follow-up
There will be no follow-up in this acute study.

Statistical analysis
Continuous variables within the baseline characteristics are expressed as median and interquartile range (IQR) or mean and standard deviation when normally distributed. Categorical variables are expressed as frequency with corresponding percentages. Continuous values were compared using the Mann-Whitney U test or unpaired t-test and categorical variables with Fisher*s Exact test. The new diagnostic modality is compared to the existing reference standard by the proportion of the true positive and true negative samples that it identifies. All reported p-values were 2 tailed, and p-values <0.05 were considered statistically significant. Statistical analyses were performed in IBM SPSS Statistics 24 and R version 3.5.1.

Study burden and risks

Risks and benefits

The participant will not benefit directly from this study. However, in the future accumulating knowledge on the effectiveness of screening for AF might be beneficial in reducing AF-related morbidity and mortality on a population level. There are no additional post-procedural limitations or visits required for this study.

Subjects will not be exposed to additional risks when choosing to participate as exercise testing was already indicated on their physician*s discretion, and the additional burden that subjects will experience is predicted to be low.

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

- 18 years of age or older;
- Willing and able to provide written informed consent;
- Scheduled for routine exercise testing, irrespective of indication;
- Willing to undergo an additional ECG recording using the Apple Watch.

Exclusion criteria

- Unwilling or unable to provide written informed consent;
- Fall-prone patients during exercise testing, e.g. due to limited mobility, visual or cognitive impairment.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-07-2019
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Apple Watch
Registration:	No

Ethics review

Approved WMO Date:	11-03-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-11-2020
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	NL68180.018.18