Accuracy of SmartWATCH-based ElectroCardioGraphic arrhythmia detection

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

Summary

ID

NL-OMON48038

Source
ToetsingOnline

Brief title
WATCH-ECG II

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 heart rhythm classification (AF or SR).

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, which utilizes similar technology, 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 outpatient 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 concern is justified and whether this commercially available noninvasive screening tool has the potential to expand the diagnostic arsenal for AF.

In the second study in this series (the first protocol (NL68180.018.18 - 2018_296) was approved on March 8th 2019), which is aimed to test the real-world performance of the Apple Watch arrhythmia detection algorithm in a resting state.

Study objective

The objective of this study is to determine the performance, as defined by sensitivity to detect AF and specificity to detect SR, of the commercially available Apple Watch-based electrocardiographic rhythm classification algorithm, validated against the gold standard 12-lead electrocardiography.

Study design

Type of study:
This is a prospective non-randomized two-arm monocenter observational study to evaluate performance of a novel commercially available diagnostic tool in adult patients that are admitted to our tertiary hospital with and without AF.

All data will be collected in the Amsterdam UMC, location Academic Medical Center in Amsterdam. All participants will be asked for written informed consent prior to enrolment.

Sample size:
Apple Inc. released a document on their website with results of an internal (unpublished) study reporting a sensitivity of 85.2% and specificity of 90.5% when including unreadable/unclassifiable results from the Apple Watch.(6) In this real-world study, we assume the sensitivity and specificity might be slightly lower. We therefore calculated that 265 enrolled patients in each study arm (i.e., 530 patients in total) will provide enough data to determine diagnostic accuracy. Patients with known AF are included to ensure an adequate prevalence of AF in the total study population (0.5).

Study methodology:
During their admission to the inpatient clinic, but before undergoing 12-lead electrocardiography, eligible subjects will be informed about the study. Only patients who are already planned for 12-lead ECG testing or who have continuous 12-lead ECG monitoring will be screened for participation. Hence, the conduct of this study will not influence the indication for ECG testing and will therefore not bring to light any newly diagnosed arrhythmias, that might otherwise have gone unnoticed. 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.

Rhythm classification with the investigational device will be performed simultaneously with the 12-lead ECG recording. In case of participation, the subject will receive the device on their left wrist and place their right index finger on the crown of the watch, as indicated by the manufacturer. In case this not possible, the right arm may be used instead. Participants will be assisted by the investigator in the Apple Watch placement and instructed to keep their arm still, for instance by resting it on a table or leg. An electrocardiographic registration of around 30 seconds will be made, after which the device algorithm indicates the registered heart rhythm, being either SR or AF (or unclassifiable or unreadable). This process may be repeated up to three times in total, allowing for practice in adequate sample acquisition. The 12-lead ECG 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.

A research fellow will be present to aid in device positioning and to record its findings on the anonymized electronic case report form (eCRF), along with baseline characteristics on age, gender, BMI and medical history.
Rhythm classification of the concurrent 12-lead ECG (using the same categories as the device) will be performed by two investigators independently and will serve as the reference 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.

Investigational product
The algorithm under investigation is featured within the rhythm detection application of the Apple Watch series 4 (released September 2018 by Apple Inc., Cupertino, CA, USA), and has obtained clearance by the Food and Drug Administration (FDA) as a class II medical device.

Follow-up
There will be no follow-up in this acute study. This study does not require any follow-up visits or additional data collection beyond their current admission.

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. Of these baseline data, continuous values are compared using the Mann-Whitney U test or unpaired t-test and categorical variables with Fisher*s Exact test.
Sensitivity and specificity will be calculated from contingency tables containing information about the test results (SR, AF and unclassifiable/unreadable) of both the gold standard and investigational test. Sinus rhythm could be wrongfully interpreted by the device as AF, counting as a false-positive in our analysis. Conversely, AF could be labelled as sinus rhythm, which would count as a false-negative.
The new diagnostic modality is thereby compared to the existing reference standard by the proportion of the true positive and true negative samples that it identifies. All reported p-values will be 2 tailed, and p-values <0.05 are considered statistically significant. Statistical analyses will be performed in IBM SPSS Statistics 24 and R version 3.5.1.

Study burden and risks

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 electrocardiography was already indicated on their physician*s discretion, and the additional burden that subjects will experience is predicted to be low.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

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;
- Must have an indication to undergo routine 12-lead ECG testing;
- Willing to undergo an additional simultaneous ECG recording using the Apple Watch.

Exclusion criteria

- Unwilling or unable to provide written informed consent.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-08-2019
Enrollment:	530
Type:	Actual

Ethics review

Approved WMO

Date:	06-08-2019
Application type:	First submission
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	NL69856.018.19