A study to describe the effectiveness of arrhythmia analysis software for screening of Sinus rhythm, Atrial Fibrillation and premature beats in light skin-and dark skin tone patients

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

Summary

ID

NL-OMON54431

Source
ToetsingOnline

Brief title
Huawei Afib study

Condition

- Cardiac arrhythmias

Synonym
Cardiac arrhythmias

Research involving
Human

Sponsors and support

Primary sponsor: Huawei Device Co., Ltd
Source(s) of monetary or material Support: Huawei Device Co.;Ltd.

Intervention

Keyword: Cardiac arrhythmias, Skin Tone, Smartwatch

Outcome measures

Primary outcome

Sensitivity and specificity of a series of three measurements to detect atrial fibrillation, premature heart rate and sinus rhythm.

a. Sensitivity and Specificity of Atrial Fibrillation Recognition

b. Sensitivity and Specificity of Premature Heart Rate Recognition

c. Sensitivity and specificity for identifying sinus rhythms.

Secondary outcome

Performance Endpoints

To measure the sensitivity and specificity of three consecutive measurements and of a single measurement to detect atrial fibrillation, premature heartbeat and sinus rhythm, single measurement results from arrhythmia analysis software are compared with the interpretation results from the simultaneous ECG recording.

Sensitivity and specificity of a single measurement to detect atrial fibrillation, premature heartbeat and sinus rhythm.

a. Sensitivity and Specificity of Recognition of Atrial Fibrillation by Single Measurement

b. Sensitivity and Specificity of Recognition of Premature Heart Rate by Single

Measurement

c. Sensitivity and specificity for identifying sinus rhythms in a single

measurement

Safety Endpoints

To determine safety, software failure rates and the incidence of adverse and

serious adverse events are recorded.

1. Software error rate (e.g. failures in getting a readout, delivering output,

etc.)

2. Incidence of Device or Procedure Adverse and Serious Adverse Events

Study description

Background summary

The intelligent portable arrhythmia detection device has advantages of portability, real-time performance and low cost, and a user can take measurements at any time, enabling early detection of arrhythmias. With this information, a doctor can be approached in time for further diagnosis and/or treatment.

In this open and controlled clinical study, the functioning of the Cardiac Arrhythmia Analysis App is tested on patients with either a very light skin tone or a very dark skin tone. The skin color is important, since the measurement takes place on the basis of light by means of. photoplethysmograph, (PPG sensor).

In this study adults, older than 18 years, can participate with or without cardiac arrhythmias.
The subject will undergo at least 3 45-second ECG measurements, and a maximum of 10 45-second measurements. The measurements with the EKG device are compared with the results of the cardiac arrhythmia analysis app.

Study objective

The device, the cardiac arrhythmia software, is intended to record, store and analyze the heart rate data collected by a PPG sensor to provide the user with notifications of events that indicate an irregular heart rhythm. The information is not intended for diagnosis and users should consult a physician if they are concerned about the information provided.

Study design

An open, single center, controlled clinical trial of the effectiveness and safety of the arrhythmia analysis app.

Study burden and risks

The patient is charged with wearing a smartwatch for a maximum of 1 hour. The following risks may arise during this period:
1. A skin reaction after contact with the wearable, including skin allergy, redness or itching of the electrode joint or any part of the wearable that touches the skin.

2. This clinical trial is being initiated during the COVID-19 pandemic. The same wearable device will be used on multiple patients. There is a risk of virus transmission if an infectious patient wears the device and it is used on the next patient without proper disinfection.

The following steps are taken to mitigate the above risks:
• No additional risk management measure for the risk of skin reactions due to low impact and low probability.
• Smartwatches are wiped with a 70% ethanol solution between uses on different patients to reduce the risk of cross-contamination.

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

1. Age >18 of any sex; 2. Wrist circumference 140 mm - 210 mm; 3. Fitzpatrick skin type 1, 2, 5, or 6 (pre-screening); 4. Melanin Index (MI) <150 or >350 as measured on the inner arm; 5. One of the following conditions, based on past 3 months' history or screening electrocardiogram: a. Normal sinus rhythm; b. Persistent or permanent or onset atrial fibrillation; c. Frequent (>5 beats per minute) premature beats or ongoing premature beats; 6. Willing and able to provide voluntary, written informed consent.

Exclusion criteria

1. Patients using pacemakers or implantable cardioverter defibrillators (ICDs);
2. Patients with atrioventricular block or bundle branch block;
3. Patients with sinus tachycardia, significant sinus bradycardia, significant sinus arrhythmia, sinus arrest or sick sinus syndrome;
4. Interpositional premature beats, dual-law premature beats, triple-law premature beats, border premature beats or escape beat heart rhythm patients;
5. Patients with atrial tachycardia, atrial flutter, ventricular tachycardia, ventricular flutter or ventricular fibrillation;
6. Patients with resting heart rate less than 50 times/minute or more than 110 times/minute;
7. Patients with tremor disease or chorea disease that are difficult to cooperate in completing the examination while remaining still;
8. Bullous disease or generalized rash, and other patients not suitable for surface electrode recording;

9. Patients with skin allergies to alcohol;
10. Patients with skin infectious diseases;
11. Patients with a history of mental illness or cognitive impairment;
12. Patients who have participated in other clinical trials that may affect this trial within the past 30 days;
13. Concomitant medication that might interfere with study results;
14. Other situations where the researchers consider it inappropriate for a patient to take part in the trial.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-04-2022
Enrollment:	84
Type:	Actual

Medical products/devices used

Generic name:	Arrhythmia Analysis App
Registration:	No

Ethics review

Approved WMO

Date:	27-01-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	15-06-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL78353.000.21

Study results

Date completed:	10-11-2023
Results posted:	21-05-2024

Summary results
Trial ended prematurely

First publication
12-04-2024