Multi-Centre based study Recognition of Atrial Fibrillation with the Corsano CardioWatch 287-2 System.

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

Summary

ID

NL-OMON57378

Source
ToetsingOnline

Brief title
COR-AF Study

Condition

- Cardiac arrhythmias

Synonym
abnormal heart rhythm, arrhythmia, Atrium fibrillation

Research involving
Human

Sponsors and support

Primary sponsor: Corsano Health B.V.
Source(s) of monetary or material Support: Financiering door Corsano Health B.V.

Intervention

Keyword: AI-based wristband, Atrial Fibrillation, Remote Monitoring, Validation research

Outcome measures

Primary outcome

Atrial fibrillation or atrial flutter (AF) episodes among 30 seconds intervals detected on (1) 24-48 hour ECG Holter or short in-clinic 12-lead ECG, and (2) within the CardioWatch 287-2 photopleythsmography signal, and (3) within the CardioWatch 287-2 single-lead ECG spot-check(s).

Secondary outcome

AF of greater than 6 minutes, 1 hour, 6 hours, and 12 hours duration detected by (1) an ECG-holter monitor, and (2) the CardioWatch 287-2 photoplethysmography signal. Additional secondary endpoints include (3) compliance with single-lead ECG alerts and required ECG attempts, together with AF confirmations based on single-lead ECG and the HR compared to reference; (4) assessment of primary outcomes in light of demographic differences based on subgroups for gender; skin color; BMI, and ethnicity; and (5) assessment of primary outcomes in light of other factors impacting device performance including patient activity and signal quality.

Study description

Background summary

AF is the most common cardiac arrhythmia and is associated with increased morbidity and mortality due to thromboembolic complications. AF can fluctuate over time and may be asymptomatic or episodic. Therefore, accurate and continuous monitoring of AF is crucial for optimal diagnosis, treatment, and

prevention of cardiovascular events.

However, conventional methods for measuring AF have several limitations. AF detection usually relies on electrocardiography (ECG), which records the electrical activity of the heart. However, ECG requires electrodes attached to the chest or limbs, which can be uncomfortable or inconvenient for long-term monitoring. Moreover, ECG may miss paroxysmal or silent AF episodes that occur sporadically or without symptoms.

Wearable devices are emerging as a promising alternative to conventional methods for measuring AF. Wearable devices can measure AF continuously and non-invasively by using novel sensors and algorithms that do not require a cuff or electrodes. Wearable devices can also enable remote monitoring and data transmission to health care providers or researchers. However, wearable devices need to be evaluated against standard methods in different clinical settings and patient populations.

The Corsano CardioWatch 287-1 is a CE-MDR certified and clinically validated vital signs monitoring bracelet. It is able to continuously measure pulse rate, inter-beat intervals, breathing rate , sleep and activity. The Corsano CardioWatch 287-2, an iteration on the 287-1, adds electrocardiogram (ECG), oxygen saturation (SpO2), galvanic skin response (GSR), core body temperature and non-invasive blood pressure (NIBP).

The Corsano CardioWatch Corsano 287-2 has been submitted to laboratory tests against internationally recognized standards for the monitoring of pulse rate, respiratory rate, SpO2, GSR, temperature and ECG. Additionally, the RECAMO (NL83281.000.22) study has been performed to investigate the performance in a non-controlled remote care setting. However, due to the nature of the study few periods with (paroxysmal) AF became available. Furthermore, all data was collected in a single centre with a low variety in demographics and ethnicities.

Study objective

The current trial aims to assess and validate atrial fibrillation detection and monitoring by the Corsano CardioWatch 287-2 in a remote setting across multiple international centres.

By:
a) To compare episodes of atrial fibrillation across 30-second intervals detected by the Corsano CardioWatch 287-2 with episodes of atrial fibrillation detected by conventional Holter monitoring across 24-48 hours or short in-clinic 12-lead ECG based on the positive predictive value, negative predictive value, sensitivity and specificity.
b) Comparing the number of atrial fibrillation episodes greater than 6 minutes, 1 hour, 6 hours, and 12 hours duration detected by the CardioWatch 287-2 and

with the number of these specific episodes detected by conventional Holter across 24-48 hours days. As well as to assess primary outcomes in light of demographic subgroups, patient activity and the signal quality index.

Study design

This concerns a multi-center, single-arm, diagnostic accuracy study. Four different groups of patients will be approached for participation in the trial:

Group A:
ECG holter monitoring will be compared to continuous monitoring by the Corsano CardioWatch 287-2 across 24-48 hours to assess whether the amount and duration of AF episodes detected by the investigational device correspond to an ambulatory ECG reference across various demographic groups. Detection of atrial fibrillation with the Corsano CardioWatch 287-2 is done by optical photoplethysmography (PPG), after which atrial fibrillation can be confirmed with a 30-second ECG measurement. Additionally, all participants will be asked to perform 10 single-lead ECG*s at standard timepoints (every 2 hours when awake) across the 24-48 hours.

Group B:
Patients with a known diagnosis of (paroxysmal) atrial fibrillation presenting to the clinic for routine follow-up evaluation will be asked to eligibly participate in ambulatory ECG monitoring as well as continuous monitoring by the Corsano CardioWatch 287-2 across 24-48 hours.
Group B was added to ensure that a considerable amount of the included data includes periods with atrial fibrillation. As the results of a prior study (RECAMO study NL83281.000.22) show that the amount of patients in Group A with periods of atrial fibrillation is limited (7.0%).

Group C:
Patients with a known diagnosis of (paroxysmal) atrial fibrillation registered in a patient organisation for patients with AF will be asked to eligibly participate in ambulatory ECG monitoring as well as continuous monitoring by the Corsano CardioWatch 287-2 across 24-48 hours. For this group two (virtual) visits will be scheduled before (visit a) and after (visit b) the study period.
In visit a) additional information regarding the study will be provided and potential alarm signals will be screened to ensure the patient does not participate in the trial in case direct medical attention is required. If the patient does not show any alarm signals they will be asked to provide informed consent. Once informed consent is provided all materials will be mailed to them via postal services after which they can perform the measurements and return the materials via postal services. In visit b) the results will be provided to the patient, and if necessary the patient will be recommended to seek medical attention.

Group D:
Participants in this group will wear the CardioWatch 287-2 during the standard 12-lead ECG recordings conducted in the outpatient clinic. Patients will be asked to perform a manual ECG spot-check with the investigational device during (if not feasible directly before), and immediately following the 12-lead ECG. Furthermore, the CardioWatch 287-2 will be worn for at least 5 minutes prior to and following the 12-lead ECG. Although these recordings are brief, this group was included to enhance the study population's size and demographic diversity while minimizing the burden on both patients and hospital staff. This group is expected to consist of both non-AF and AF patients, providing valuable insights into the investigational device's performance in a setting similar to its intended real-world application.

Groups C and D were added to limit the additional workload for hospital staff and ensure inclusion of a diverse patient population from different demographic and ethnical groups.

Study burden and risks

The study involves wearing of the Corsano CardioWatch 287-2 and a standard ECG-holter for 24-48 hours or short in-clinic 12-lead ECG, which does not impose a significant risk to the patient but does call on the patient's time and effort. The study is necessary for the evaluation of the Corsano CardioWatch 287-2 in a remote care setting across a variaty of demographic groups. The device has the potential to improve the monitoring of atrial fibrillation, which can help prevent strokes and provide additional monitoring strategies for atrial fibrillation. This potential can only be realized by conducting the study and having patients wear the wristband as well as a 12-lead ECG-holter at home.

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

* Patients with symptoms indicative of cardiac arrhythmias receiving 24-48 hour ECG holter for home monitoring per doctor prescription OR previous diagnosis of arrhythmia presenting to the clinic for routine follow-up evaluation
* Age >= 22 years old
* Able to provide informed consent.
* Patients with symptoms indicative of cardiac arrhythmias
* Proficient in written and spoken Dutch or English, defined by self-report of comfort reading, writing, and speaking Dutch or English.

Exclusion criteria

* Clinical conditions that in the opinion of the Investigator would compromise the safety of the patient or ability to complete the protocol;
* Unable to wear the Corsano CardioWatch 287 due to reasons such as allergic reactions, wounds, amputations etc.;
* Unable or not willing to receive ambulatory ECG monitoring;
* Unable or not willing to sign informed consent;

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	CardioWatch 287-2
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	27-03-2025
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL87967.000.24